In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 18, 2023

KATHLEEN COOPER-LOHER,	*	No. 18-769v
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on the Record; Dismissal; Influenza ("Flu") Vaccine; Granuloma Annulare ("GA"); Significant Aggravation
Respondent.	*	

Carol L. Gallagher, Carol L. Gallagher, Esquire, LLC, Somers Point, NJ, for Petitioner.
Debra A. Filteau Begley, United States Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On May 31, 2018, Kathleen Cooper-Loher ("Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program ("Program" or "Vaccine Program").[2] Petitioner alleges that she received the influenza vaccine on November 9, 2015, "causing her to suffer with granuloma annulare" ("GA").[3] Pet. at 1, ECF No. 1. Petitioner further alleges her GA was exacerbated "following a mandated influenza vaccine administered on November 7, 2016." *Id.*

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99–660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] Granuloma annulare is "a group of benign, usually self-limited granulomatous diseases of unknown etiology with both localized and disseminated varieties, most often seen in children and young adults. The lesions chiefly involve the dermis and are perforating papules or subcutaneous nodules grouped in rings. Histopathologic findings include palisading macrophages surrounding foci of necrobiosis of the dermis." *Dorland's Illustrated Medical Dictionary* 1, 803 (32nd ed. 2012) [hereinafter "*Dorland's*"]. A papule is "a small circumscribed, superficial, solid elevation of the skin less than 1 cm (0.5 cm according to some authorities) in diameter." *Id.* at 1373. Necrobiosis is "swelling, basophilia, and distortion of collagen bundles in the dermis, sometimes with obliteration of normal structure, but without actual necrosis[.]" *Id.* at 1234.

Petitioner filed a motion for a ruling on the record on June 9, 2022. Pet'r's Mot. for Ruling [hereinafter "Pet'r's Mot."], ECF No. 62. For the reasons stated below, Petitioner's case is hereby **DISMISSED**.

I. Procedural History

Over the next several months after filing her petition on May 31, 2018, Petitioner filed seven medical record exhibits in support of her claim, an affidavit, and her first statement of completion. Pet'r's Exs. 1–8, ECF Nos. 7, 9–11, 13. Thereafter, on November 19, 2018, Respondent filed a status report, in which he identified outstanding medical records needed to evaluate Petitioner's claim. ECF No. 14. These records included pre-vaccination health records, post-vaccination records, and photos of Petitioner's rash that were referenced in prior documents. *See id.*

In response, on November 30, 2018, Petitioner filed photos and a pre-vaccination medical record. Pet'r's Exs. 9–10, ECF No. 16. She filed employment records and an amended statement of completion on January 3, 2019. Pet'r's Ex. 11, ECF Nos. 17–18. On April 9, 2019, Petitioner filed an additional medical record. Pet'r's Ex. 12, ECF No. 22. Respondent filed his Rule 4(c) report on May 6, 2019, in which he recommended against compensation. Resp't's Report at 8–9, ECF No. 24. Respondent argued that Petitioner is unlikely to satisfy her burden for compensation because "it is not clear when [P]etitioner developed GA." *Id.* at 6. Respondent continued that "Petitioner's records document that she had chronic skin issues before her 2015 and 2016 flu vaccinations, and there are no records documenting any rash on [P]etitioner's skin until seven months after her 2016 flu vaccination." *Id.* Therefore, Respondent maintained that Petitioner's medical records do "not document either the onset or a flare of GA in association with either of her vaccines." *Id.* at 7. Petitioner filed an affidavit in response to Respondent's assertions on May 21, 2019. Pet'r's Ex. 13, ECF No. 25.

The same day, I ordered Petitioner to submit an expert report by July 22, 2019. Sched. Order, docketed May 21, 2019. Petitioner filed an expert report from Dr. Steven Rostad, his curriculum vitae, and supporting literature on July 22 and 23, 2019. Pet'r's Exs. 14–48, ECF Nos. 27–31. Additionally, Petitioner submitted two affidavits: one on her own behalf and another from a co-worker. Pet'r's Exs. 49–50, ECF Nos. 32–33. Based on these filings, I held a status conference with the parties on August 22, 2019. Min. Entry, docketed Aug. 22, 2019. During the conference, Respondent raised specific factual issues within Petitioner's expert report relating to the development and timing of her symptoms. Sched. Order, ECF No. 35. As such, Respondent indicated he did not "feel that a rebuttal expert report was necessary to demonstrate that the case should not proceed." *Id.* at 1. I awarded Petitioner thirty days to determine whether she could provide evidence corroborating the post-vaccination onset of her symptoms or to otherwise indicate how she wished to proceed. *Id.* She filed an additional medical record on September 24, 2019. Pet'r's Ex. 52, ECF No. 41.

Petitioner submitted an additional expert report and status report that were ultimately stricken from the record "because the filings d[id] not clarify issues in the case." *See* Sched. Order, ECF No. 42. The decision to strike these filings came following an agreement by the parties during a status conference held on September 25, 2019. *See id.*; *see also* Min. Entry, docketed Sept. 25,

2019. During the conference, Respondent stated his intention to file a motion to dismiss and I gave Respondent thirty days to do so. Sched. Order, docketed Sept. 25, 2019.

Respondent filed his motion to dismiss on October 28, 2019. Resp't's Mot. to Dismiss, ECF No. 47. Respondent reiterated his position articulated in his Rule 4(c) report. *Id.* He added that Dr. Rostad's expert "report is based on an incorrect timeline, excludes relevant pre-vaccination facts, assumes facts contradicted by the medical records, and relies on speculation." *Id.* at 8 (citing Pet'r's Ex. 14 at 3–4). Petitioner filed medical literature and a response to Respondent's motion on November 5, 2019. Pet'r's Ex. 53, ECF No. 48; Pet'r's Resp., ECF No. 49. In Petitioner's response, she noted that "there remain genuine issues of material facts in the instant case." Pet'r's Resp. at 1. Therefore, a dismissal would not be appropriate, given the procedural posture of the claim. *Id.*

Although Respondent styled his motion as a motion to dismiss, it was more akin to a motion for summary judgment. In ruling on such a motion, "special masters must draw on every inference concerning disputed facts in favor of the nonmoving party." *See* Order at 4, ECF No. 50 (internal citations omitted). Further, "if to dispose of the case[,] the special master must resolve conflicts of fact or weigh conflicting evidence," summary judgment is inappropriate. *Id.* I denied Respondent's motion to dismiss and noted that the onset date of Petitioner's GA is a material fact in dispute. *Id*. I further noted that Petitioner's theory of causation was also contested. *Id.* Therefore, I was unable to resolve the case or make the necessary credibility findings, resolve conflicts of fact, and weigh conflicting evidence in favor of or against Petitioner without a complete evidentiary record. *Id.* at 5. I then ordered Petitioner to file an expert report including a detailed discussion on symptom onset and but-for causation. Order at 1, ECF No. 50-1.

After one motion for extension of time, Petitioner filed the expert report and curriculum vitae of Dr. Richard Knierim on June 4, 2021, followed by supporting medical literature on June 8, 2021. Pet'r's Exs. 54–55, ECF No. 52; Pet'r's Exs. 56–60, ECF No. 53. Respondent filed the responsive expert report and curriculum vitae of Dr. Markus Boos on October 8, 2021, along with supporting medical literature. Resp't's Exs. A, A Tabs 1–14, B, ECF No. 56. Petitioner filed a supplemental report from Dr. Knierim on November 18, 2021. Pet'r's Ex. 61, ECF No. 57. Following a status conference to discuss further proceedings, Petitioner filed a motion for ruling on the record on June 9, 2022. Pet'r's Mot., ECF No. 62. Respondent responded on July 13, 2022. Resp't's Resp., ECF No. 64. Petitioner filed a reply on July 20, 2022. Pet'r's Reply, ECF No. 65. This matter is now ripe for consideration.

II. Evidence

a. Medical Records

i. Pre vaccination

Petitioner's pre-vaccination history is significant for asthma and several skin-related conditions. Pet'r's Ex. 11 at 243, ECF No. 17-1. Her medical records include summaries from annual physicals conducted over several years from 2010 through 2014. *See generally* Pet'r's Ex. 9, ECF No. 16-1. Janet Bowen, a board-certified advanced registered nurse practitioner

[hereinafter "NP Bowen"], recorded assessments from Petitioner's physical exams that often included a skin evaluation. *Id.* The note from Petitioner's December 15, 2010 exam, showed that her "lower legs [presented] with granuloma annularis [sic], otherwise without suspicious lesions." *Id.* at 4. The physical the following year, on November 9, 2011, had no notation for a skin evaluation. *Id.* During the exam, however, Petitioner reported "chronic skin problems and rashes that pop[ped] up here and there due to eczema[4] and dermatitis."[5] *Id.* at 5. She stated that triamcinolone cream[6] "seem[ed] to take care of it quite well[,]" and NP Bowen prescribed Petitioner betamethasone dipropionate.[7] *Id.* On November 21, 2012, NP Bowen noted Petitioner's "forearms and upper left arm [appeared] with several areas of red, flat, macular-type[8] lesions, otherwise grossly without suspicious lesions." *Id.* at 3. NP Bowen renewed Petitioner's betamethasone dipropionate prescription. *Id.* There is no record for a physical conducted in 2013, but Petitioner's May 20, 2014 physical notes indicated that her skin was "grossly without suspicious lesions." *Id.* at 2. NP Bowen renewed Petitioner's betamethasone dipropionate cream. *Id.* Petitioner did not file records documenting any care between May 21, 2014, and November 8, 2015. She received the first flu vaccine at issue on November 9, 2015. Pet'r's Ex. 1 at 1, ECF No. 7-1.

ii. Post vaccination

There are no filed medical records documenting any treatment for Petitioner between November 10, 2015, and April 14, 2016. Petitioner's first post-vaccination medical visit occurred on April 15, 2016. Pet'r's Ex. 3 at 15, ECF No. 7-3. Petitioner presented to urgent care that day "with a rash mainly over [her] trunk, arms[,] and legs." *Id.* She disclosed "an upper respiratory illness [("URI")] starting about [two] weeks [prior]." *Id.* Petitioner reported the URI "symptoms including sinus congestion, cough and chest heaviness seemed better [after] about [one] week[;] however, [the following week], she also developed a pruritic[9] rash starting more so on the trunk and then subsequently spreading down the legs and arms." *Id.* This rash, according to Petitioner, was unlike previous hive-like irritations she has had. *Id.* An examination revealed a "very

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[4] Eczema is "any of various pruritic, papulovesicular types of dermatitis occurring as reactions to endogenous or exogenous agents. In acute types there may be erythema, edema, inflammatory infiltrates in the dermis, vesiculation, crusting, and scaling. In chronic types there may be lichenification, skin thickening, signs of excoriation; and areas of hyperpigmentation or hypopigmentation." *Dorland's* at 592. Pruritic means itchy. *Id.* at 1540. Dermatitis is generally, "inflammation of the skin." *Id.* at 494. Lichenification is "hypertrophy of the epidermis, with thickening and toughening of the skin to give it a leathery appearance, and exaggeration of its normal markings; this is caused by prolonged rubbing or scratching and may be on seemingly normal skin or on skin that has a pruritic disorder." *Id.* at 1034.

[5] *See id.*

[6] Triamcinolone cream is a "synthetic glucocorticoid used in replacement therapy for adrenocortical insufficiency and as an anti-inflammatory and immunosuppressant in a wide variety of disorders." *Dorland's* at 1959.

[7] Betamethasone dipropionate is "used topically for the relief of inflammation and pruritus in corticosteroid-responsive dermatoses." *Dorland's* at 211.

[8] Macular pertains to "macules." A macule is "a discolored skin lesion that is not elevated above the surface." *Dorland's* at 1094.

[9] *See supra,* note 4 (defining pruritic).

minimally raised, erythematous,[10] maculopapular[11] rash." *Id.* at 16. The visit record noted that the areas on Petitioner's abdomen and back were "more coalesced into a larger collection of lesions." *Id.* There were smaller, more isolated patches on her legs. *Id.* Petitioner was diagnosed with "likely" viral exanthem[12] and prescribed hydroxyzine[13] and prednisone.[14] *Id.* Petitioner indicated that she had used hydroxyzine in the past and was more comfortable with it than prednisone, which she would "hold off on." *Id.* There are no filed medical records documenting any treatment for Petitioner between April 16, 2016, and August 28, 2016.

On August 29, 2016, Petitioner sought treatment from dermatologist Dr. Robert Aylesworth and his physician's assistant, Stephanie Keller, for a five-month history of "a rash to the chest and flanks." Pet'r's Ex. 4 at 1, ECF No. 7-4. Petitioner reported that her symptoms "started out with a viral URI that her entire family had[,] and many family members ended up with a rash." *Id*. Her family members' rashes quickly resolved, but hers lasted "[six to eight] weeks, [went] away, then [came] back," though "[e]ach recurrence [wa]s less bothersome than the previous." *Id.* Petitioner had self-treated unsuccessfully with topical steroids, Benadryl,[15] and Atarax.[16] *Id.* She reported a history of psoriasis.[17] *Id.* Dr. Aylesworth assessed Petitioner with dermographism[18] and recommended a biopsy. *Id.* Petitioner refused the procedure and wanted to rely on Zyrtec.[19] *Id.* Dr. Aylesworth prescribed 10 mg tablets, twice daily. *Id.*

On November 7, 2016, Petitioner received another flu vaccine, mandated by her employer. Pet'r's Ex. 1 at 1. Petitioner did not file records documenting any care between November 8, 2016, and June 14, 2017.

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[10] Erythematous refers to skin reddening due to the accumulation of blood in dilated capillaries, as in inflammation; a rash. *Dorland's* at 643.

[11] Maculopapular is "characterized by both macules and papules." *Dorland's* at 1095.

[12] Viral exanthem is a skin rash related to a viral infection. *Dorland's* at 656.

[13] Hydroxyzine is an antihistamine. *Dorland's* at 884. The term "antihistamine" can "broadly include any agent that blocks any histamine receptor, in practice it is usually used to denote those blocking H_1 receptors (H1 receptor antagonists), which are the drugs conventionally used to treat allergic reactions and are also components of many cough and cold preparations." *Id.* at 107.

[14] Prednisone is a "synthetic glucocorticoid derived from cortisone; used as an anti-inflammatory and immunosuppressant in a wide variety of disorders." *Dorland's* at 1509.

[15] Benadryl is the trademark preparation of diphenhydramine hydrochloride, which is "used for the symptomatic treatment of allergic symptoms[.]" *Dorland's* at 208, 523.

[16] Atarax is the trademark preparation of hydroxyzine hydrochloride. *Dorland's* at 170. Hydroxyzine hydrochloride is an antianxiety agent used in the manifestations of allergic dermatoses. *Id.* at 884.

[17] Psoriasis refers to "any of a group of common chronic, squamous dermatoses with variable symptoms and courses; some are inherited. Principal histologic findings are [] microabscesses and [] pustules; also seen are rounded, circumscribed, erythematous, dry, scaling patches of various sizes, covered by gray, silvery, or white, umbilicated, lamellar scales. The most common sites are extensor surfaces, nails, scalp, genitalia, and the lumbosacral region." *Dorland's* at 1547.

[18] Dermographism is "a type of physical urticaria in which moderately firm stroking or scratching of the skin with a dull instrument produces a wheal with a red flare on each side." *Dorland's* at 499.

[19] Zyrtec is the "trademark for preparations of cetirizine hydrochloride." *Dorland's* at 2097. Cetirizine hydrochloride is a nonsedating antihistamine used in the treatment of allergies. *Id.* at 334.

Petitioner returned to Dr. Aylesworth on June 15, 2017, complaining of "itchy, red bumps all over her entire body," and she explained that topical steroids and antihistamines had not been helpful. Pet'r's Ex. 4 at 2. Petitioner stated that her "condition ha[d] been present since Fall [of] 2015, and her current flare ha[d] been present since Feb[ruary of] 2017." *Id.* She continued that it "ha[d] become more severe each time she ha[d] a flu shot and when she has gotten a cold." *Id.* Petitioner reported that the rash had changed from "a fine, faint rash and is now multiplied and increased in size. It bleeds from scratching." *Id.* Petitioner rarely used Zyrtec because it "made her very sleepy." *Id.* She stated that she used "betamethasone [dipropionate] twice daily which help[ed] a bit." *Id.* Upon exam, Dr. Aylesworth noted "[s]oft, small[,] enlarged nodes to axilla and crural folds[, and r]ed, eroded papules[20] up to 1.5cm in size . . . scattered to [Petitioner's] chest, axilla, arms, and legs." *Id.* Dr. Aylesworth listed Petitioner's clinical diagnosis as "[n]eoplasm[21] of uncertain behavior" and noted to "[rule out pityriasis lichenoides et varioliformis acuta ("PLEVA")[22] versus cutaneous T-cell lymphoma]."[23] *Id.* He prescribed triamcinolone cream. *Id.*

The same day, Dr. Aylesworth ordered a skin biopsy. *Id*. at 3. Dermatopathologist Dr. Seun L. Kim performed a biopsy on June 17, 2017. *Id.* at 31. The biopsy results revealed "mild compact hyperkeratosis[24] and mild mounding parakeratosis[.]"[25] *Id.* at 30. There was evidence of "equivocal focal spongiosis[26] with associated occasional intraepidermal lymphocytes." *Id.* Tissue staining showed numerous small T-cells that "favor[ed] a reactive pattern." *Id*. at 6, 30. Dr. Kim's surgical pathology report listed Petitioner's diagnosis as "[p]alisaded interstitial histiocytic dermatitis[27] with increased dermal mucin."[28] *Id.* at 31. He added in the comments that "[t]he histology is favored to represent a palisaded and necrobiotic granulomatous dermatitis,[29] most likely [GA] given the associated increased mucin." *Id.*

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[20] *See supra,* note 3 (defining papules).

[21] Neoplasm is "any new and abnormal growth; specifically[,] a new growth of tissue in which the growth is uncontrolled and progressive[.]" *Dorland's* at 1239.

[22] PLEVA is "an acute or subacute, sometimes relapsing, widespread macular, papular, or vesicular eruption that tends to crusting, necrosis, and hemorrhage, which heals to leave pigmented depressed scars, followed by a new crop of lesions." *Dorland's* at 1451.

[23] Cutaneous T-cell lymphoma is "a group of lymphomas including a spectrum of disorders, all of which exhibit both clonal expansion of malignant T lymphocytes and malignant infiltration of the skin. The lymphocytes have been arrested at varying stages of differentiation into helper cells, and skin infiltration is often the chief or only manifestation of disease." *Dorland's* at 1086. Lymphoma is any neoplastic disorder of the lymphoid tissue; also called a malignancy. *Id.*

[24] Hyperkeratosis is also known as a callus. *Dorland's* at 890.

[25] Parakeratosis refers to the "persistence of the nuclei of the keratinocytes into the stratum corneum[.]" *Dorland's* at 1376. A keratinocyte is an epidermal cell that synthesizes keratin. *Id.* at 979. Keratin is a scleroprotein that makes up the constituents of the epidermis, hair, nails, and other tissues. *Id.* The stratum corneum is the outermost layer of the epidermis, consisting of cells that are dead. *Id.* at 1779.

[26] Spongiosis refers to the "intercellular edema of the epidermis, giving the tissue a spongelike appearance due to the formation of microvesicles." *Dorland's* at 1755.

[27] Palisaded interstitial histiocytic dermatitis can be defined as follows: palisaded refers to "the arrangement of cells or cellular structures side by side in rows, like pickets in a fence[.]" *Dorland's* at 1365. Interstitial dermatitis or interstitial granulomatous dermatitis is "a rare skin condition that presents with erythematous and violaceous plaques, and may be associated with pruritus and pain." *See* Z. Ahmed et al., *Interstitial granulomatous dermatitis successfully treated with etanercept,* 15 AM. J. CASE REP. 94–96 (2014).

[28] Dermal mucin refers to the most abundant macromolecules in mucus. *Dorland's* at 1185.

[29] *See supra,* notes 3, 27 (defining necrobiosis and palisaded and granulomatous dermatitis).

On June 30, 2017, Petitioner returned to Dr. Aylesworth and explained that she had a "flu vaccine and viral illness since [her] last visit and feels much worse now. The condition remains unchanged." *Id.* at 6. An examination revealed red papules with erosions on Petitioner's back and chest. *Id*. Dr. Aylesworth diagnosed Petitioner with GA, administered a Kenalog injection,[30] and ordered testing for an underlying autoimmune disease. *Id*. Testing for rheumatoid factor,[31] Lyme disease,[32] and Sjögrens antibodies[33] was negative. *Id*. at 28. An anti-nuclear antibody ("ANA")[34] screening was also negative. *Id.* During a return visit to Dr. Aylesworth on July 19, 2017, Petitioner reported improvement following the Kenalog injection, and she was prescribed methotrexate.[35] *Id.* at 8. Petitioner's records show that she improved with methotrexate but suffered a flare whenever she became ill with a viral infection. *See id.* at 9–10. In October of 2017, Petitioner obtained a note from Dr. Aylesworth that stated a flu vaccine can induce a flare of GA, and this was "likely to be the case w[ith] this patient." Pet'r's Ex. 5 at 3, ECF No. 7-5.

Thereafter, Petitioner continued to take methotrexate for her skin condition through October of 2018. Pet'r's Ex. 12 at 1, ECF No. 22-1. During a visit with Dr. Aylesworth on January 4, 2019, Petitioner stated that when she stopped her medication, her condition "worsened a bit," but that she did not feel the need to restart any medication and was only rarely applying steroid cream. *Id*. During a return visit to Dr. Aylesworth on March 27, 2019, Petitioner was noted to be stable with only occasional "red spots" that she treated with steroid cream. *Id*. at 2. Petitioner has not filed additional medical records.

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[30] A Kenalog injection refers to the trademark preparation of triamcinolone acetonide, which is used "as an antiinflammatory and immunosuppressant in a wide variety of disorders[,]" including allergies and asthma. *Dorland's* at 978, 1959.

[31] Rheumatoid factor refers to "antibodies directed against antigenic determinants, i.e., Gm, in the Fc region of the IgG class of immunoglobulins . . . . Rheumatoid factors may be of the IgM, IgG, or IgA classes of immunoglobulins[.]" *Dorland's* at 676.

[32] Lyme disease is "a recurrent, multisystemic disorder caused by the spirochete *Borrelia burgdorferi*; vectors for human infection are the ticks *Ixodes scapularis* and *I. pacificus.* It begins in most cases with erythema chronicum migrans (at least 5 cm in diameter), often accompanied by fatigue, malaise, chills, fever, headache, and regional lymphadenopathy, followed after several weeks or months by highly variable manifestations that may include musculoskeletal pain, involvement of the heart and the nervous system, and conjunctivitis and other eye abnormalities. Persistent infection, which may last for months or years, is characterized by arthritis of large joints and, in some cases, neurologic manifestations, including chronic axonal polyneuropathy, ataxia, and spastic paraparesis." *Dorland's* at 538.

[33] Sjögren's antibodies are immunoglobulins specific to that disease. *Dorland's* at 100. Sjögren's syndrome is "a symptom complex of unknown etiology, usually occurring in middle-aged or older women, marked by the triad of keratoconjunctivitis sicca with or without lacrimal gland enlargement, xerostomia with or without salivary gland enlargement, and the presence of a connective tissue disease, usually rheumatoid arthritis but sometimes systemic lupus erythematosus, scleroderma, or polymyositis. An abnormal immune response has been implicated." *Id.* at 1848.

[34] ANAs are "antibodies directed against nuclear antigens; ones against a variety of different antigens are almost invariably found in systemic lupus erythematosus and are frequently found in rheumatoid arthritis, scleroderma (systemic sclerosis), Sjögren syndrome, and mixed connective tissue disease. Antinuclear antibodies may be detected by immunofluorescent staining. Serologic tests are also used to determine antibody titers against specific antigens." *Dorland's* at 101.

[35] Methotrexate is a folic acid antagonist used as an "antipsoriatic and antiarthritic in the treatment of severe, recalcitrant, disabling psoriasis and severe rheumatoid and psoriatic arthritis." *Dorland's* at 1151.

b. Affidavits

i. Petitioner's First Affidavit

Petitioner filed her first affidavit on June 5, 2018, and provided a chronology of the progression of her condition post vaccination. Pet'r's Ex. 2 at 1, ECF No. 7-2. At the time of both flu vaccinations at issue, Petitioner was employed as an operating room registered nurse. *Id.* Seasonal flu vaccinations were a mandatory condition for her continued employment. *Id.* Petitioner stated that "gradually beginning approximately two to three weeks" following her November 9, 2015 flu vaccination, Petitioner "notice[d] that [her] skin had become very pruritic." *Id.* The itching "worsened to the point that [Petitioner] could not wear anything tight." *Id.* She added that "scratching made the itching worse," although she "did not notice any rashes or lesions." *Id.* In March of 2016, Petitioner "contracted a cold and [her] skin erupted in a fine, extremely itchy rash." *Id.*

The itching continued, and Petitioner "could[not] sleep at night." *Id.* at 2. She stated that "[a]nything that touched [her] skin would exacerbate [the itching] to the point [she] would be in tears." *Id.* at 1. Petitioner used home remedies, including "baking soda baths, oatmeal baths, topical steroids, Benadryl, hydroxyzine, Claritin,[36] elimination diets, calamine lotion, and aloe vera[,]" without success. *Id.* at 2. Approximately one month later, Petitioner went to seek medical treatment at urgent care and was prescribed hydroxyzine and oral prednisone. *Id.* She "did not take the prednisone at first, and the hydroxyzine did not help with either the rash or the itching." *Id.*

Petitioner did not see a dermatologist until August of 2016, noting that "there [wa]s only one dermatologist covering the entire northern Wisconsin region, and appointments [we]re booked out for months." *Id.* At that time, according to Petitioner, her "rash was in remission, although there were still some small affected areas." *Id.* Petitioner noticed that her "skin would break out whenever [she] contracted a virus." *Id.*

Petitioner stated that at the time of her November 7, 2016 flu vaccination, she "was recovering from a virus, and [her] skin was badly broken out and very pruritic." *Id.* at 1–2. Despite her condition, Petitioner was ordered to "take the vaccine or [she would] get fired." *Id.* at 3. She stated that following her vaccination, she "again broke out worse than [she] ever had[,]" including with lesions that "have not abated[.]" *Id.* Eventually, the lesions "became disfiguring, leaving scars." *Id.* Petitioner noted that her "coworkers were shocked at the state of [her] skin." *Id.* She continued that she "never missed work," but "[t]here were many times that [she] had to be excused from [her] duties because [she] was so miserable that [she] would dissolve into tears." *Id.*

When medical treatment did nothing to alleviate the itching, Petitioner "tried alternative methods, such as acupressure, acupuncture, a vegan diet, tanning, and again did not receive any relief." *Id.* Petitioner sought out another dermatologist and was diagnosed with "interstitial granulomatous dermatitis, a form of [GA]." *Id.* After steroids did not help, Petitioner stated that she was prescribed methotrexate, which "did help to mitigate the symptoms, [but did] not alleviat[e] them all together." *Id.*

[36] Claritin refers to the trademark preparation of loratadine, which is a nonsedating antihistamine. *Dorland's* at 368, 1074.

This condition has affected Petitioner's ability to show affection to family members because physical contact is "unbearable." *Id.* at 4. Her hair is thinning, and she takes uncomfortably cold showers to relieve the itching. *Id.* In an unsuccessful effort to reduce stress and achieve remission, Petitioner retired from her job in January of 2018. *Id.* Petitioner "realized that this very well may be a lifelong condition." *Id.* She stated in her affidavit that she "truly believe[s] that the flu vaccine [she] received on November 9, 2015, caused [her] injuries." *Id.* at 5.

ii. Petitioner's Second Affidavit

Petitioner filed a second affidavit "as a response to the Respondent's Rule 4(c) Report." Pet'r's Ex. 13 at 1. Petitioner acknowledged that she "had skin issues in the past, but never of the severity that [she] had after the [November 9, 2015] flu vaccine, and not the same type." *Id.* She identified those "previous skin issues [as] eczema or contact dermatitis that were easily treated with topical creams." *Id.* She explained that "[t]he lesions [she] developed after the flu vaccines were entirely different and debilitating, and nothing worked to treat it except methotrexate and time." *Id.*

Petitioner acknowledged that there were long periods of time during which she did not seek medical treatment, even as her itching was described as "unbearable" and "bringing her to tears." *Id.*; *see also* Pet'r's Ex. 2 at 1–2. Petitioner blamed her high insurance deductibles and copays as contributing factors to her delay in seeking treatment. Pet'r's Ex. 13 at 1. She explained that "[a]nother factor that contributed to the lag in the early symptoms and the [first post-vaccination] office visits" was a lack of dermatologists in the area and that she had "an excruciatingly long wait to receive an appointment." *Id.* at 2. Petitioner asserted that treaters at the urgent clinic also misdiagnosed her condition when she sought treatment there "in the spring of 2016." *Id.* Petitioner noted "[t]hey were not doctors, they were physicians' assistants." *Id.* Petitioner maintained that she was healthy pre vaccination and asserted "[t]he absence of medical records for long periods of time indicates that [she] indeed did have an abrupt change in condition after the [November 9, 2015] flu vaccine." *Id.* at 1.

Petitioner stated that the reaction that she had following her receipt of the flu vaccination in November of 2016 is what helped her realize "the [November 2015] flu vaccine had caused [her] problem." *Id.* at 2. Petitioner asserted that "in autoimmune disorders of this type, sometimes at the beginning of the symptoms, no one really knows what caused it." *Id.* at 3. She admitted that "she did not [know] either until [she] received the second flu vaccine [in November of 2016] and [her symptoms] became so much worse and she thought back and remembered the timeline of [her] symptoms[]" as dating back to her November 9, 2015 flu vaccine. *Id.*

iii. Affidavit of Peggy Bessette

Ms. Bessette was a colleague of Petitioner's who provided an affidavit describing Petitioner's symptoms following her November 9, 2015 vaccination. Pet'r's Ex. 50, ECF No. 33-1. Ms. Bessette stated that Petitioner "developed a rash covering a large portion of her torso and upper and lower extremities." *Id.* at 1. Ms. Bessette noted that the rash "appeared as small, reddened, raised bumps and was so numerous in number that in places it appeared as large[,] reddened blotches." *Id.* Petitioner reported to Ms. Bessette that the rash was "extremely

uncomfortable," and that Petitioner "would have long scratch marks on her body that would be open and bleeding" from the itching. *Id.* According to Ms. Bessette, the rash "lasted well over a year and was still present when [Ms. Bessette] terminated [her] employment." *Id.* She noted that "[n]othing [Petitioner] tried brought her relief from this debilitating rash and itch." *Id.*

c. Additional Filed Evidence[37]

i. Emailed Communications

On November 14, 2016, Petitioner sent an email to Cynthia Vogelsang, her employee health and safety nurse. Pet'r's Ex. 5 at 1. Petitioner wanted it "on record that [she] had a severe reaction after the influenza vaccine [she] received on Monday, November 7[, 2016]." *Id.* Petitioner noted that she "already had an existing viral rash from a recent URI, and after the vaccine it [was] exacerbated to the point that the itching was agonizing for the rest of the week and weekend." *Id.* She described unbearable itching but explained she "ha[d] not seen anyone about it, because [she would] not be working [at the same medical facility] next year when the vaccines are being given, so that ma[de] it a waste of time." *Id.*

ii. Employee Records

On August 3, 2017, Petitioner filed an injury/illness report with her employer claiming that she suffered a reaction to the flu vaccine in 2015. Pet'r's Ex. 11 at 312. Petitioner admitted that she did not initially realize the cause of her condition. *Id.* She stated that she developed an itchy rash that "got worse with each exposure to a virus." *Id.* Following another flu vaccine in 2016, Petitioner stated that she got worse because "she was thereafter misdiagnosed by two doctors and now sees Dr. Aylesworth." *Id.* She explained that she has a rare skin condition and that while little is known about her condition, it is triggered by vaccines. *Id.*

Petitioner's employer denied her request for a medical exemption to the mandatory seasonal flu vaccination on September 28, 2017. Pet'r's Ex. 5 at 4. The employee health manager explained that "[i]nfluenza exemptions are reviewed using the [CDC] guidelines for contraindications." *Id.* After review, "it [was] determined that [Petitioner did] not have a contraindication to receiving the influenza vaccine." *Id.* Petitioner submitted a letter of resignation on November 6, 2017, and stated that her last day would be January 3, 2018. Pet'r's Ex. 11 at 12.

iii. Photographs

[37] Petitioner filed medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I refer only to those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x. 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

On November 30, 2018, Petitioner filed three sets of photos with hand-written notations that they were taken in April 2016, May 2017, and March 2018, respectively. *See* Pet'r's Ex. 11. The first two photos depict one extremity (not identified) and the lower abdomen. *Id.* The annotations are the same on both and state, "taken in April of 2016," and "skin after flu vaccine in 2015." *Id.* at 1–2. The clarity is poor, but there appears to be some discoloration on the skin consistent with a rash that is maculopapular. *Id.* The next three photos are of Petitioner's abdomen and a side view of her torso. *Id.* at 3–5. The notations on these photos state they were "taken in May of 2017" and depict "skin after flu vaccine in 2016." *Id.* These images better illustrate the redness of the rash and the individual nodules, which were widespread. *Id.* The last two photos are of the front and back of Petitioner's torso taken of the "skin in [March of] 2018 after halving [Petitioner's] dose of methotrexate." *Id.* at 6–7. The notes accompanying these photos also state that the lesions had returned and that there was scarring. *Id.* There is a marked lessening in severity in these last two photos. *See id.*

d. Expert Reports

i. Petitioner's Expert, Dr. Steven Rostad

Petitioner filed an expert report authored by Dr. Steven Rostad. Pet'r's Ex. 14, ECF No. 27-1. Dr. Rostad is "a pathologist, board-certified in anatomic and neuropathology and a Fellow of the College of American Pathologists." *Id.* at 1. He received his B.A., *magna cum laude*, from Harvard College in 1978 and his medical degree from the University of Washington in 1983. Pet'r's Ex. 15 at 1–2, ECF No. 28-1. Dr. Rostad completed a fellowship in neuropathology, followed by a residency in anatomical pathology at the University of Washington. *Id.* at 1. He then began his thirty-year practice as a neuropathologist with Swedish Medical Center and as an anatomic pathologist with CellNetix Pathology. *Id.* Retired since 2018, Dr. Rostad "currently review[s] consultations predominantly of a medical-legal nature." Pet'r's Ex. 14 at 1. In the past five years, he has "provided expert testimony in approximately [twelve] cases," including "approximately [six] medico-legal cases and given testimony in [three]." *Id.* at 2. Dr. Rostad admitted that he has "not directly treated patients with skin problems," but he "routinely . . . evaluated tissue samples for skin issues, including inflammatory problems." *Id.* at 1. He has seen hundreds of GA cases over his career and "is qualified to address the pathologic criteria." *Id.* Dr. Rostad also noted that he has not published on GA but has "attended multiple conferences, which have discussed skin disorders in general and this topic in particular, along with its differential diagnosis." *Id.* He has published in topics including temporal lobe seizures, the varicella-zoster virus, with a focus in AIDS patients, pituitary adenoma pathogenesis, and breast tissue DNA. Pet'r's Ex. 15 at 3–6.

After a discussion of Petitioner's medical history, Dr. Rostad "concu[rred] with the excellent workup, [GA] diagnosis[,] and comments outlined in Dr. Kim's [surgical pathology] report." Pet'r's Ex. 14 at 7. In support of Petitioner's GA diagnosis, Dr. Rostad highlighted "the presence of palisading dermal histocytes/macrophages (granulomas) with associated necrobiosis." *Id.* He also thought Dr. Kim's "concern for an infectious etiology" was appropriate. *Id.* According to Dr. Rostad, a review of Petitioner's histologic evaluation showed a "reduce[d] possibilit[y] of acid-fast and fungal infections." *Id.* He opined that "[t]he histologic findings are not those of a contact or allergic dermatitis, which had been considered in her past medical history." *Id.* Also,

Dr. Rostad concluded that PLEVA was adequately considered but not diagnosed. *Id.* Without further comment, Dr. Rostad added that other rheumatological conditions "were apparently not considered likely as they were not discussed" by Petitioner's treaters. *Id.*

Dr. Rostad defined GA as a "noninfectious granulomatous disease of the skin . . . typically characterized by an annular[38] arrangement of erythematous to flesh-colored papules." *Id.* This is supported by Dr. Peggy Cyr's article, *Diagnosis and Management of Granuloma Annulare*.[39] Pet'r's Ex. 17, ECF No. 28-3. Dr. Cyr noted that "[d]espite the dramatic appearance of this cutaneous eruption, it generally is asymptomatic; however, there may be some mild pruritus." *Id.* at 1. Petitioner filed *Pruritus*[40] by Dr. Scott Moses, which describes the symptom as "a common manifestation of dermatologic disease." Pet'r's Ex. 24 at 1, ECF No. 28-10. Dr. Moses explained that "[a] single mechanism cannot explain all causes of pruritus." *Id.* However, he listed several dermatological causes, exposure-related causes, and pregnancy-related causes. *See generally id.* Dr. Moses also identified systemic causes of pruritus, including lymphoma,[41] HIV, anemia,[42] cancers, parasitic infections, viral infections, neuropathy,[43] and scleroderma.[44] *Id.* at 4.

Dr. Rostad continued that GA can be generalized, patchy/macular, subcutaneous, or perforating. Pet'r's Ex. 14 at 8. He opined that Petitioner developed generalized granuloma annulare ("GGA"), "consisting of hundreds of papules that are either discrete or confluent, but typically do not show any annular arrangement." *Id.* Dr. Cyr explained in her article that GA is most commonly localized and self-limited, while disseminated GGA is widespread. Pet'r's Ex. 17 at 1. Dr. Cyr also noted that "[t]he cause of [GA] is unknown but it has been reported to follow trauma, malignancy, viral infections,[45] insect bites, and tuberculosis skin[46] tests." *Id.* In these cases, "a delayed-type hypersensitivity reaction and cell-mediated immune response are hypothesized." *Id.* Dr. Rostad expanded on Dr. Cyr's list and asserted that GA "has been linked to trauma, animal or insect bites, vaccinations, drugs, sun exposure, tuberculosis, various viral infections[,] and chronic stress." Pet'r's Ex. 14 at 8.

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[38] Annular means shaped like a ring; circular. *Dorland's* at 94.
[39] P. R. Cyr, *Diagnosis and Management of Granuloma Annulare,* 74(10) AM. FAM. PHYS. 1729–35 (2006).
[40] S. Moses, *Pruritis,* 68(6) AM. FAM. PHYS. 1135–43 (2003).
[41] *See supra,* note 23 (defining lymphoma).
[42] Anemia is "a reduction below normal in the concentration of erythrocytes or hemoglobin in the blood, measured per mm^3 or by volume of packed red cells per 100 mL of blood; it occurs when the equilibrium is disturbed between blood loss (through bleeding or destruction) and blood production." *Dorland's* at 78.
[43] Neuropathy is "a functional disturbance or pathologic change in the peripheral nervous system, sometimes limited to noninflammatory lesions as opposed to those of neuritis[.]" *Dorland's* at 1268.
[44] Scleroderma is "chronic hardening and thickening of the skin[.]" *Dorland's* at 1679.
[45] Dr. Cyr listed HIV, Epstein-Barr virus, and herpes zoster as viruses that have been associated with the development of GA. Pet'r's Ex. 17 at 1.
[46] Tuberculosis refers to "any of the infectious diseases caused by species of *Mycobacterium* and characterized by tubercle formation with caseous necrosis in the tissues . . . . Any organ may be affected, but in humans the lung is the major seat of the disease [] and is the usual portal of entry into the body." *Dorland's* at 1979.

Petitioner filed several articles that discussed GA generally and its pathology. The De Paola et al.[47] article described GA as one of "a broad group of distinct reactive inflammatory conditions." Pet'r's Ex. 16 at 1, ECF No. 28-2. The authors noted that GA "is a benign, self-limiting, relatively common dermatosis" and has "significant associations with systemic diseases." *Id.* The cause is unknown, but GA "has been reported following traumas, malignancy, viral infections, insect bites, and tuberculosis skin tests." *Id.* Although the authors reiterated that "[t]he pathogenesis of GA remains still obscure[, p]ossible pathogenetic factors suggested include humoral and delayed type hypersensitivity, vascular damage, metabolic disorder, or primary collagen[48] and/or elastin[49] alteration mediated through an immunologic mechanism." *Id.* Piette and Rosenbach[50] began their article by noting that there are "a number of hypotheses regarding the underlying etiology of GA; however, most of these hypotheses are supported by relatively limited evidence." Pet'r's Ex. 57 at 1, ECF No. 53-2; *see also* Resp't's Ex. A, Tab 12, ECF No. 56-13. The authors acknowledged associations between GA and some systemic diseases and vaccinations. Pet'r's Ex. 57 at 5. Specifically, they identified case studies involving the Bacillus Calmette-Guérin ("BCG")[51] vaccine, hepatitis B, tetanus, and diphtheria vaccines. *Id.*

While acknowledging that "[t]he trigger for the development of GA is unknown," Dr. Rostad stated it is one of three types of abnormal immune responses: "overactive (i.e. hypersensitivities), ineffective (immunodeficiency)[,] and inappropriate (autoimmunity)." Pet'r's Ex. 14 at 8. Specifically, he explained that GA is "a lymphocyte-mediated hypersensitivity type IV mechanism, or delayed type hypersensitivity ("DTH") reaction." *Id.* The Vaillant and Ramphul[52] article explained that a "[g]ranulomatous-type hypersensitivity results from the persistence within macrophages of intracellular pathogens or other substances that the cell is unable to process or destroy." Pet'r's Ex. 23 at 2, ECF No. 28-9. The "histology shows a typical epithelioid-cell granuloma" with visible, giant cells "in the center of the lesion, [and] surrounded by a cuff of lymphocytes." *Id.* at 3. Dr. Rostad asserted that the presence of activated CD4+ T-helper cells is evidence of an immune process. Pet'r's Ex. 14 at 8. He noted that "[i]t is thought that GA is a DTH reaction to primary collagen or elastin destruction." *Id.* Collagen destruction occurs when macrophages within the lesions release proinflammatory cytokines. *Id.* The most important cytokines being "[tumor necrosis factor ("TNF")]-alpha and beta IL-2, and [granulocyte-macrophage colony-stimulating factor] ("GM-CSF")." *Id.*

Dr. Rostad cited the Lynch and Barrett[53] study that explains this phenomenon. Pet'r's Ex. 22, ECF No. 28-8. The study stated that altered collagen is thought to be an antigenic trigger that

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[47] M. De Paola et al., *Granuloma Annulare, Autoimmune Thyroiditis, and Lichen Sclerosus in a Woman: Randomness or Significant Association?,* 2013 CASE REP. DERMATOL. MED. 1–4 (2013).
[48] Collagen is "any of a family of extracellular, closely related proteins occurring as a major component of connective tissue, giving it strength and flexibility." *Dorland's* at 384.
[49] Elastin is "a scleroprotein that is the essential constituent of elastic connective tissue." *Dorland's* at 598.
[50] E.W. Piette & M. Rosenbach, *Granuloma annulare: Pathogenesis, disease associations and triggers, and therapeutic options,* 75 J. AM. ACAD. DERMATOL. 467–79 (2016).
[51] The Bacillus Calmette-Guérin vaccine "is administered by scarification or intradermal or intracutaneous injection to tuberculin-negative individuals for prevention of tuberculosis." *Dorland's* at 190.
[52] ANGEL A. JUSTIZ VAILLANT & KAMLESHUN RAMPHUL, DELAYED HYPERSENSITIVTY REACTIONS 1–8 (StatPearls eds., 2022).
[53] J. M. Lynch & T.L. Barrett, *Collagenolytic (necrobiotic) granulomas: part 1 – the 'blue' granulomas,* 31 J. CUTAN. PATHOL. 353–61 (2004).

attracts T-helper ("Th") cells, which then release proinflammatory cytokines. *Id.* at 3. The Th cells "also secrete macrophage-inhibiting factors, causing macrophages to persist in the area." *Id.* The authors contend that the apoptotic[54] macrophages in the lesion are evidence of a DTH reaction that incites macrophages. *Id.* The lesions are self-limiting because cell destruction "is controlled by activation-induced apoptosis in lymphocytes and macrophages." *Id.* In GGA cases, "lesions have palisading granulomas" with "[t]hick and multilayered basal lamina around lesional capillaries [that suggest] a more pronounced immune reaction is responsible." *Id.* at 4. In *Vaccine-associated Hypersensitivity,*[55] authors McNeil and DeStefano discussed the effects of this type of immune system stimulus. Pet'r's Ex. 48, ECF No. 31-4. They noted that "[l]arge local vaccine reactions secondary to T-cell infiltration are often associated with prolonged and very effective immunity." *Id.* at 2. The reactions are described as "self-limiting conditions that do not contraindicate administration of future doses (e.g., booster doses) of the same vaccine." *Id.*

Other biological mechanisms for GA following cancer treatment mentioned briefly in Dr. Rostad's report include a "reaction to a vaccine immunotherapy for metastatic melanoma," and check point inhibitors that "block the inhibitory signal of CD4+ Th1 cells." Pet'r's Ex. 14 at 13 (citing Pet'r's Exs. 43–44, ECF Nos. 30-9–30-10).[56] This disruption "subsequently lead[s] to T cell activation and proliferation, resulting in aggregation and activation of macrophages, i.e.[,] granuloma formation." *Id.*

Dr. Rostad further relied on the Vaillant and Ramphul article in support of his assertion that this type of DTH reaction (granulomatous) would appear approximately 21–28 days following contact with the inducing antigen, as opposed to a contact or tuberculin reaction that would both appear within 48 to 72 hours. *Id.* at 8 (citing Pet'r's Ex. 23 at 1). He explained that the "[d]iseases caused by DTH responses tend to be chronic, such as with leprosy,[57] tuberculosis, schistosomiasis,[58] sarcoidosis[,][59] and Crohn's disease."[60] *Id.* The McNeil and DeStefano article also provided an appropriate temporal relationship between a vaccine and DTH reaction. *See* Pet'r's Ex. 48. The authors stated that "[d]elayed-type reactions occur commonly within hours or days after exposure, although symptom onset can be delayed up to [two to three] weeks." *Id.* at 2.

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[54] Apoptotic or apoptosis refers to the "morphologic pattern of cell death affecting single cells," marked by shrinkage of the cell; "a mechanism for cell deletion in the regulation of cell populations[.]" *Dorland's* at 118.

[55] M. McNeil & F. DeStefano, *Vaccine-associated hypersensitivity,* 141 J. ALLERGY CLIN. IMMUNOL. 463–72 (2018).

[56] A. Aria et al., *Chronic granulomatous reaction in patients receiving vaccine immunotherapy for metastatic melanoma*, 4 JAAD CASE REPS. 87–90 (2018); J. Wu et al., *Granuloma annulare associated with immune checkpoint inhibitors,* 32(4) J. EUR. ACAD. DERMATOL. VENEREOL. 124–30 (2018).

[57] Leprosy is "a slowly progressive, chronic infectious disease caused by *Mycobacterium leprae* and characterized by granulomatous or neurotrophic lesions in the skin, mucous membranes, nerves, bones, and viscera, with a broad spectrum of clinical symptoms." *Dorland's* at 1022.

[58] Schistosomiasis is an acute and chronic parasitic disease caused by blood flukes (trematode worms) "of the genus *Schistosoma*." *Dorland's* at 1675.

[59] Sarcoidosis is "a chronic, progressive, systemic granulomatous reticulosis of unknown etiology, characterized by hard tubercles . . . . It can affect almost any organ or tissue, including the skin, lungs, lymph nodes, liver, spleen, eyes, and small bones of the hands and feet." *Dorland's* at 1668.

[60] Crohn's disease is "one of the principal forms of inflammatory bowel disease, a chronic granulomatous disease of the gastrointestinal tract of unknown etiology[.]" *Dorland's* at 531.

According to Dr. Rostad, Petitioner's "symptoms occurr[ed] within two-three weeks of the November 2015 influenza [vaccine]." Pet'r's Ex. 14 at 15. Dr. Rostad continued, "GGA or DTH eventually presented [four] months post vaccination," and "[t]his interval fits with more recent experience with DTH reactions." *Id.* He concluded that "[t]he 2016 flu vaccination caused acceleration of [Petitioner's] disease." *Id.*

The logical sequence of cause and effect for Petitioner's GA is summarized by Dr. Rostad in five parts:

1) Petitioner's health had been stable up until she received the 2015–2016 influenza vaccination on November 9, 2015,
2) Antigen stimulation caused an immune response, noted within two-three weeks [post vaccination], which most likely started locally, eventually became systemic in the form of relentless itching,
3) The flu vaccine immune response, which began near the injection site, eventually triggered a delayed systemic lymphocyte-mediated hypersensitivity type IV or DTH response in the form of GA,
4) The GA and related symptoms progressed and were retriggered following additional immune challenges, including upper respiratory infections and the 2016–2017 flu vaccination,
5) Once powerful immune suppression and antigen containment were instituted, her condition improved considerably.

Id. at 9. Dr. Rostad stated that his "theory is based on knowledge of the pathogenesis of DTH and GA." *Id.* at 15.

Dr. Rostad illustrated how Petitioner's clinical presentation was consistent with his theory. He noted that Petitioner's first symptom (itching) "began gradually approximately two to three weeks after receiving the November 2015 vaccine." *Id.* at 9. Dr. Rostad noted that itchiness "is a nonspecific clinical symptom, sometimes reported following vaccination." *Id.* He added that "it is a common finding with GA" but acknowledged that "[a] formal medical evaluation for her pruritus was not obtained." *Id.* He characterized Petitioner's URI that occurred four months later, in March of 2016, as an immune challenge causing her pruritic condition to progress to a rash. *Id.* He asserted that "the rash and pruritus showed correlation with the initial vaccination and appeared to change in relative intensity together[, meaning] it is most likely that they are manifestations of the same disease, namely DTH (GA)." *Id.* Petitioner's "more intense reactivation of her symptoms and DTH (GA)" followed her November 7, 2016 vaccination. *Id.* His conclusion that Petitioner suffered "[a] DTH-like reaction [] was supported by the histopathology and immunocytochemical biopsy results." *Id.* at 15.

A significant section of Dr. Rostad's report then provided a detailed explanation of "autoimmune diseases or autoimmune syndromes induced by adjuvants [("ASIA")]." *Id.* at 10. He opined that "[v]accine antigens or adjuvants could have caused [P]etitioner's condition." *Id.* He stated that "the aluminum adjuvant literature shows overlap to those in [P]etitioner's case, including the granulomatous, DTH-like histopathology, potential delayed time intervals between vaccination and development of lesions, a weak association with autoimmune disease (as with

GA)[,] and the presence of systemic symptoms."[61] *Id.* Dr. Rostad admitted that "[t]he exact allergen that triggered the proposed DTH reaction in [Petitioner] is unknown." *Id.*

Dr. Rostad acknowledged that the "number of reports relating vaccines and GA is limited." *Id.* at 13. Dr. Rostad asserted, however, that GA "has been associated with vaccination and other immune reactions." *Id.* In support of this contention, Dr. Rostad noted "one case of GA following influenza vaccination[]" and "[eleven] previous cases of GA following other vaccines." *Id.* The Suzuki et al.[62] study examined the case of a 76-year-old woman "suffering from a tender subcutaneous nodule on her left upper arm," one month following an influenza vaccination in the same arm. Pet'r's Ex. 38 at 1, ECF No. 30-4. The authors suggested that a specific, unidentified "vaccine antigen may evoke a T cell-mediated, granuloma-inducing immune reaction in predisposed individuals." *Id.* at 2. The patient in that case study had "diabetes mellitus,[63] a disease potentially promoting granuloma formation, such as necrobiosis lipoidica[64] and GA[; therefore, the patient] might [have] be[en] susceptible to vaccine-induced GA." *Id.* The eleven cases that do not involve the influenza vaccine include patients that range from infancy to 58 years old and include hepatitis B, BCG, tetanus, diphtheria, and rubella vaccinations. Pet'r's Ex. 40 at 3, ECF No. 30-6.[65] Three of the eleven patients were adults and experienced long-term skin rashes following hepatitis B booster vaccinations. *Id.* The three adult patients included a 51-year-old with resolution at four years and a 20-year-old that still had symptoms after one year. *Id.*

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[61] Petitioner's expert spent several pages of his initial report explaining ASIA and asserting that ASIA was the biological mechanism for Petitioner's GA. In her reply brief to her motion for a ruling on the record, however, Petitioner stated "adjuvants were not [P]etitioner's expert's theory in this case." Pet'r's Reply at 3. Furthermore, the ASIA theory has never been successfully asserted in the Program. *See D'Angiolini v. Sec'y of Health & Hum. Servs.*, 122 Fed. Cl. 86, 102 (2015) (upholding special master's "determin[ation] that ASIA does not provide[] a biologically plausible theory for recovery"), *aff'd*, 645 F. A'ppx. 1002 (Fed. Cir. 2016); *Garner v. Sec'y of Health & Hum. Servs.*, No. 15-063V, 2017 WL 1713184, at *8 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) (observing that the ASIA theory "is, at a minimum, incomplete and preliminary—and therefore unreliable from an evidentiary standpoint"); *Rowan v. Sec'y of Health & Hum. Servs.*, No. 10-272V, 2014 WL 7465661, at *12 (Fed. Cl. Spec. Mstr. Dec. 8, 2014) (rejecting the ASIA theory because it "is not a proven theory" and no "persuasive or reliable evidence" supports it); *Johnson v. Sec'y of Health & Hum. Servs.*, No. 10-578V, 2016 WL 4917548, at *7–*9 (Fed. Cl. Spec. Mstr. Aug. 18, 2016) (rejecting a theory that "any adjuvant [is] capable of causing any autoimmune disease," finding it "overbroad, generalized, and vague, to the point that it could apply to virtually everyone in the world who received a vaccine containing an adjuvant and then at some time in their lives developed an autoimmune disease"). Therefore, a detailed discussion of this mechanism is not included in this Decision.

[62] T. Suzuki et al., *Subcutaneous granuloma annulare following influenza vaccination in a patient with diabetes mellitus,* 32 DERMATOL. SINICA 55–57 (2014).

[63] Diabetes mellitus is "an autoimmune disease that results in the destruction of beta cells of the pancreas, leading to loss of the ability to secrete insulin." *Dorland's* at 506.

[64] Necrobiosis lipoidica is "a degenerative disease of dermal connective tissue, characterized by erythematous papules or nodules in the lower leg and sometimes elsewhere, forming shiny yellow to red plaques that are covered with telangiectatic vessels and have a depressed center. More than half of affected patients have diabetes mellitus, although the condition appears the same in both diabetic and nondiabetic patients." *Dorland's* at 1234.

[65] T. Nomiyama et al., *Granuloma annulare-like reaction to the bacillus Calmette-Guerin vaccination,* 54 AUSTRAL. J. DERMATOL. 4–7 (2013).

The Yang,[66] Nomiyama et al.,[67] and Lee et al.[68] studies all contemplated GA following receipt of the BCG vaccination. Pet'r's Exs. 39–41, ECF Nos. 30-5–30-7. The Yang et al. study involved a three-month-old infant "who developed a bacilli-containing granuloma over the vaccination site and subsequent granuloma annulare-like eruptions over the arm and back." Pet'r's Ex. 39 at 1. One month post vaccination, "[a] reddish papule" was noted at the injection site and "gradually became an indurated nodule." *Id.* The following month, "several scattered erythematous papules and annular plaques developed." *Id.* The patient's "lesions came and went for another [four] weeks and finally resolved completely with no further relapse over an 18-month follow-up period." *Id.* The other two articles also described infants who experienced a reaction at the injection site, approximately one month post vaccination, followed by an eruption of lesions all "over the body" during the second month post vaccination. Pet'r's Ex. 40 at 1; Pet'r's Ex. 41 at 1. With corticosteroid treatment, the lesions resolved after three and one months, respectively. Pet'r's Ex. 40 at 3; Pet'r's Ex. 41 at 1. The multiple "reports of GA as a complication of BCG vaccination" suggested to Dr. Rostad "that GA might occur in relation to the physical trauma of vaccination or a cell-mediated delayed hypersensitivity reaction against a certain antigen of the vaccine." Pet'r's Ex. 14 at 13. Dr. Rostad also referenced "extensive cutaneous granulomas" following a live rubella virus vaccination. *Id.* (citing Pet'r's Ex. 42, ECF No. 30-8).[69]

ii. Petitioner's Expert, Dr. Richard Knierim

Dr. Knierim received his B.A., *magna cum laude*, from Columbia Union College in 1966, and his medical degree from Loma Linda University in 1970. Pet'r's Ex. 55 at 3, ECF No. 52-2. He completed a residency in anatomic and clinical pathology at University of Washington Affiliated Hospitals. *Id.* at 5. Up until approximately 2020, Dr. Knierim held board certifications in both specialties. *Id.* He has also been board certified in cytopathology and dermatology. Pet'r's Ex. 54 at 2, ECF No. 52-1. Dr. Knierim has been a pathologist for Swedish Medical Center since 1990. Pet'r's Ex. 55 at 1. He has also worked for CellNetix as a dermatopathologist and as a clinical associate professor of pathology at the University of Washington School of Medicine. *Id.* He was the chief of anatomic pathology for the Madigan Army Medical Center and the United States Army Hospital in Okinawa, Japan. *Id.* at 3. Dr. Knierim stated in his written expert report that he "has been mostly retired from the practice of pathology" since 2018. Pet'r's Ex. 54 at 2. Dr. Knierim noted that he has "not directly treated patients with skin problems." *Id.* He expressed that he has qualifications "to address the pathologic criteria of [GA], and ha[s] reviewed triggers associated with the onset of GA." *Id.*

In his report dated June 4, 2021, Dr. Knierim stated that he had reviewed Petitioner's medical records and sample slides, filed evidence, Dr. Rostad's expert report, and Respondent's Rule 4(c) Report. *Id.* at 2–4. Dr. Knierim noted that Petitioner's "skin lesions prior to November 2015 [are] not relevant." *Id.* at 5. He opined that "[i]t is not at all surprising that a correct diagnosis

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[66] S. Yang & C. Chang, *Bacilli-containing granuloma with subsequent granuloma annulare-like eruptions following Bacillus Calmette-Guérin vaccination,* 59 PED. & NEONATOL. 525–26 (2018).
[67] *See* T. Nomiyama et al., *supra* note 65.
[68] S. Lee et al., *Generalized Granuloma Annulare in Infancy Following Bacillus Calmette-Guerin Vaccination,* 23(3) ANN. DERMATOL. 319–22 (2011).
[69] C. Bodemer et al., *Live rubella virus vaccine long-term persistence as an antigenic trigger of cutaneous granulomas in patients with primary immunodeficiency,* 20 CLIN. MICROBIOL. INFECT. 656–63 (2014).

of disseminated [GA] was made by a pathologist and dermatologist months after the second immunization." *Id.* To support the length of time between the onset of Petitioner's skin condition and her proper diagnosis, Dr. Knierim stated that he had "seen important diagnoses made only at autopsy." *Id.* He concluded "that it is more probable than not that a serious form of [GA], the disseminated form, was triggered in [Petitioner] by [her] influenza immunizations." *Id.* at 6.

Dr. Knierim conceded in his November 15, 2021 report, that GA "was present in [Petitioner] years prior to the 2015 and 2016 influenza vaccinations." Pet'r's Ex. 61 at 1, ECF No. 57-1. In Dr. Knierim's supplemental report he quoted a communication from Petitioner he received in October of 2021. *Id.* at 2. It was not filed in this case, but the relevant excerpt from Dr. Knierim's report is copied here:

> I had granuloma annulare healing on my legs in 2010. I did, only it was a much more benign form that caused small non itchy bumps in a circular pattern in my legs and much purplish discoloration. In 2010, when they were noted by my nurse practitioner, I had had the healing lesions for a couple of years (hence annulare, it takes years to heal). They had started appearing AFTER A FLU SHOT I RECEIVED IN 2007. I didn't put two and two together when it happened, but I did once I got the same thing, only in a much more virulent form, after the other flu shots. I had even asked Dr. Aylesworth, (whom I had seen around 2008 or so, because of the mysterious lesions on my legs) if he still had records that far back, and he said no, they had been destroyed. It could prove a relation with the flu vaccine, and the autoimmune response resulting in the granuloma annulare skin lesions.

Id. After he received this additional information, Dr. Knierim changed his opinion from his first report and asserted that Petitioner's GA "was significantly exacerbated by mandated influenza vaccine[s she] received [on] November 9, 2015[,] and November 7, 2016." *Id.* In support of his position, Dr. Knierim noted Dr. Aylesworth's October 11, 2017 contention that Petitioner "ha[d] disseminated [GA] and vaccination can induce flaring of this disorder and this is likely to be the case with this patient." *Id.* (citing Pet'r's Ex. 5 at 3). According to Dr. Knierim, the decision to use a more aggressive treatment, methotrexate, in July 2017 "is evidence of GA which at that time was severe and difficult to treat." *Id.* at 3. Dr. Knierim also cited Petitioner's affidavit and her filed, post-vaccination "photographs[70] [to] support the diagnosis of a quite severe case of disseminated GA." *Id.* at 2. Dr. Knierim concluded that there is "[a] possibility that [an] influenza vaccine received by [Petitioner] in 2006 was a factor [in the development of her condition that] cannot be excluded." *Id.* at 3.

e. Respondent's Expert, Dr. Markus Boos

Dr. Markus Boos received his B.A. degree, *summa cum laude*, with a double major in biology and economics from Kalamazoo College in 2000. Resp't's Ex. B at 1, ECF No. 56-16. After completing a Ph.D. program in immunology at the University of Chicago, he received his

[70] Handwritten notes on the photos state that they were taken in April of 2016 after the flu vaccine in 2015; in May of 2017 after the flu vaccine in 2016; and in March of 2018 "after halving [her] dose of methotrexate – lesions returned." *See generally* Pet'r's Ex. 10.

medical degree from the same institution with honors in 2010. *Id.* Dr. Boos completed his residency in dermatology and served as the chief resident at the University of Pennsylvania. *Id.* He currently serves as an associate professor of dermatology and pediatric dermatology at the University of Washington and Seattle Children's Hospital. *Id.* at 1–2. He is board certified in dermatology and pediatric dermatology. Resp't's Ex. A at 1, ECF No. 56-1. Dr. Boos noted that he has seen "a wide spectrum of inflammatory skin diseases, including [approximately fifty to sixty pediatric and adult cases of GA]." *Id.* Dr. Boos further noted his doctoral research in immunology. *Id.* He asserted that his "background in immunology informs [his] understanding of the molecular pathogenesis of many skin conditions that are driven by immune processes." *Id.*

Dr. Boos used the *Bolognia's Dermatology* reference text to define GA as "a benign, usually self-limited, cutaneous disease that classically presents a[n] arciform to annular plaques located on the extremities of young people." *Id.* at 6 (citing Resp't's Ex. A, Tab 3 at 1, ECF No. 56-4).[71] Continuing his reliance on the *Bolognia* definition, he noted that the plaques may range from skin colored to purple and "are usually asymptomatic." *Id.* While GGA is a less common form, it "has a later age of onset, poorer response to therapy, and increased prevalence [in patients with] the HLABw35 allele." *Id.* (citing Resp't's Ex. A, Tab 3 at 2). Dr. Boos noted that various diseases, including diabetes, hyperlipidemia,[72] and "less commonly[,]" cancers and viral infections, were comorbidities in some patients, but "a plurality of patients had no identifiable associated diseases or triggers." *Id.* (citing Resp't's Ex. A, Tab 10 at 1, ECF No. 56-11).[73] He also noted that "the pathogenesis of [GA] is unknown," although "it has been proposed that GA represents a delayed-type hypersensitivity reaction." *Id.* at 7.

In Petitioner's case, Dr. Boos wrote, "it is not at all clear that [Petitioner's post-vaccination GA] was a new diagnosis." *Id.* at 9. He referenced her December 15, 2010 annual exam, during which GA was observed and noted. *Id.* (citing Pet'r's Ex. 9 at 4–5). He explained that GA is "a relatively rare diagnosis." *Id.* Furthermore, "it is extremely unlikely that a non-dermatologist would use this term without a patient having received this diagnosis previously." *Id.* at 9–10. Dr. Boos stated that Petitioner "described waxing and waning of her skin condition in accordance with her stress levels," but he noted that "we have no further context/record from before 2010 to confirm this." *Id.* at 10.

When Petitioner's pruritus appeared post vaccination in 2015, "she did not develop any sort of a skin eruption at that time." *Id.* Dr. Boos explained that "[i]tchy skin alone, without any evidence of a rash, is not consistent with a GA flare[,] and itch is not recognized as a prodromal symptom of GA." *Id.* Petitioner's April 2016 complaint of a rash occurred "following an [URI two] weeks prior," and approximately "[four to five] months" post vaccination. *Id.* Although Dr. Boos did not review the photos of Petitioner's April 2016 rash, he assumed the rash was a manifestation of her GA for the sake of argument. *Id.* Without citing to a particular article or case study, Dr. Boos asserted that "every reported case described onset of GA from within [one] week to [two] months of receiving said vaccination." *Id.* In his experience, "non-specific flares of

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[71] JEAN BOLOGNIA, BOLOGNIA'S DERMATOLOGY 2 (Joe Jorizzo et al. eds., 3rd ed. 2012).

[72] Hyperlipidemia is "a general term for elevated concentrations of any or all of the lipids (fats) in the plasma." *Dorland's* at 891.

[73] T.M. Nordmann et al., *A Monocentric, Retrospective Analysis of 61 Patients with Generalized Granuloma Annulare,* 236(4) DERMATOL. 369–74 (2020).

inflammatory skin disorders can be triggered by viral infections or vaccination, but typically do so within approximately a week of stimulation[.]" *Id.* Therefore, Petitioner's "URI present immediately preceding the eruption is more likely to have triggered [her] rash" in April of 2016. *Id.*

Dr. Boos also pointed to inconsistencies between Petitioner's statement and that of her former colleague, Ms. Bessette. *Id.* He noted Ms. Bessette's statement that Petitioner, "[f]ollowing the injection of a flu shot on November 9, 2015, . . . developed a rash covering a large portion of her torso and upper and lower extremities [that] . . . caused an exceptionally itchy sensation." *Id.* (quoting Pet'r's Ex. 50 at 1). He then highlighted that "not even [P]etitioner state[d] that she developed a rash immediately after that vaccination." *Id.* at 11. The fact that Ms. Bessette's affidavit was completed "nearly [four] years after the incident in question" also caused Dr. Boos to question its accuracy. *Id.* Instead, Dr. Boos opined that "no cutaneous findings were present until [five] months after [Petitioner received] the influenza vaccine in November [of] 2015 and[,] in fact[,] the initial eruption in March/April 2016 was temporally associated with a viral URI[.]" *Id.* He continued, "attributing the development of GA to [Petitioner's November 9, 2015 flu] vaccination therefore strains plausibility." *Id.* Petitioner's account of rash onset to Dr. Aylesworth on August 29, 2016, as beginning "five months earlier[,] puts the onset in late March or early April [of] 2016." *Id.* Dr. Boos also noted Petitioner's report that her rash had resolved at the time of her August 2016 visit with Dr. Aylesworth, but that "it continued to flare every [six to eight] weeks." *Id.* (citing Pet'r's Ex. 4 at 1). Dr. Boos stated that Petitioner "did not have a rash during her August 29, 2016 exam, and [P]etitioner did not return to Dr. Aylesworth until June 15, 2017, despite her claim that she developed a significantly worsened rash in November 2016." *Id.* These facts, Dr. Boos asserted, are evidence of GA flares more likely exacerbated by illness and stress without "any particular events surrounding her vaccinations." *Id.*

Petitioner's GA, in "presentation and overall course[,] is very consistent with idiopathic generalized GA[.]" *Id.* Dr. Boos noted that "[Petitioner's] age and the fact that her condition was treatment resistant and recurrent, with resolution only over [three] years, is more commonly seen in generalized GA as a whole." *Id.* Quoting *Bolognia,* Dr. Boos explained that "GA is estimated to resolve spontaneously 'within [two] years in 50% of patients, but there is a 40% recurrence rate. The duration of untreated lesions has been reported to range from a week to several decades.'" *Id.* (citing Resp't's Ex. A, Tab 3 at 3). He characterized Petitioner's GA as idiopathic that was "present years before vaccination[, with] flares associated with immune stimulation—including [URIs], stress or vaccination." *Id.* While Dr. Boos identified vaccination as a potential catalyst for flares, he hypothesized that "[i]f [Petitioner] did, in fact, suffer [] flares around the time of her vaccination[s]," these flares were minor and resolved without treatment, "in a waxing and waning pattern." *Id.* at 12.

Furthermore, "[w]ith respect to [Petitioner's] second vaccination in November 2016, she endorse[d] that she already had a flare of her condition secondary to a URI that was present at the time of vaccination." *Id.* Dr. Boos noted that Petitioner's next medical visit following this vaccination occurred in June of 2017. *Id.* During that visit, Petitioner stated that a "flare [was still] present at that time [after first] appear[ing] in February [of] 2017[.]" *Id.* at 13 (citing Pet'r's Ex. 4 at 2). Dr. Boos continued that this "again demonstrat[ed] months between [Petitioner's]

vaccination and a severe flare of her skin condition that warranted mention and [for her to seek] treatment." *Id.*

III. Summary of the Parties' Arguments

a. Petitioner's Motion for Ruling on the Record and Reply

In her motion for a ruling on the record, Petitioner alleged that her November 9, 2015 flu "vaccine triggered a skin condition, [GA], and that this condition was exacerbated by a subsequent mandated influenza vaccine administered to her on November 7, 2016." Pet'r's Mot. at 1. In support of her argument, she described the appearance of a pruritic rash that appeared "within a couple of weeks of the [2015 vaccination]." *Id.* Petitioner asserted that at the time of her November 7, 2016 vaccination, "her GA had not been formally diagnosed." *Id.* at 2. Petitioner reiterated in her reply brief that "Dr. Aylesworth diagnosed [her] with GA following a skin biopsy performed on June 17, 2017." Pet'r's Reply at 1.

She highlighted the qualifications of her expert, Dr. Rostad, noting he is a board-certified pathologist that "has reviewed over 80,000 cases within surgical, autopsy, neuropathology, cytology, forensic, medical-legal[,] and pediatric specialties, including skin pathology." Pet. Mot. at 3. Notably, Petitioner mentioned that "Dr. Rostad graduated from Harvard[,] *magna cum laude*," and "[h]is curriculum vitae speaks for itself." Pet'r's Reply at 4. Petitioner stated that her expert is therefore well qualified to opine that "the appearance of the skin lesions '[was] not inconsistent with GA,'" that was "due to a vaccine DTH reaction." Pet'r's Mot. at 4. Petitioner argued that Dr. Knierim, her second expert, provided further support for her claim. *Id.* Petitioner highlighted Dr. Knierim's work as "a major in the medical corp. of the United States Army and a pathologist in the United States Army Hospital in Okinawa, Japan[.]" Pet'r's Reply at 4. Petitioner argued that her experts' theories are clearly explained in their respective reports, and they are both well qualified to form those opinions. *Id.*

Petitioner stated that the *Loving* factors are relevant to her claim that the 2016 flu vaccine significantly aggravated her GA that was initially caused by the 2015 vaccination. *Id.* at 2 (citing *Loving v. Sec'y of Health & Hum. Servs.,* 86 Fed. Cl. 135 (2009)). She also explained that she did not receive an adjuvanted flu vaccine in 2015 or 2016 and therefore, "adjuvants were not [P]etitioner's experts' theory in this case." *Id.* at 3. Petitioner concluded that her sixty exhibits, including "[three] expert reports and [thirty-eight] exhibits of medical literature" support her claim of entitlement to compensation. Pet'r's Mot. at 5. She contended that Respondent's expert, however, "has given no alternative explanation as to what could have caused [P]etitioner's GA." *Id.*

b. Respondent's Response

Respondent did not dispute Petitioner's GA diagnosis in his response to Petitioner's motion. Resp't's Resp. at 1. Indeed, Respondent first argued that Petitioner's condition predates her vaccination, according to a 2010 medical record that mentions the condition. *Id.* at 12 (citing Pet'r's Ex. 9 at 4). This, according to Respondent, is confirmed by Petitioner's admission to Dr. Knierim in October of 2021, that she "had [GA] healing on her [her] legs in 2010" and that those

lesions "started appearing after a flu shot [she] received in 2007." *Id.* at 12 n.6 (citing Pet'r's Ex. 61 at 2) (emphasis omitted). Petitioner also noted within that same communication with Dr. Knierim that she was diagnosed with GA by Dr. Aylesworth in 2008. *See id.* Respondent noted that aside from her assertions, Petitioner has not filed evidence that she received the 2007 flu vaccination, a contemporaneous adverse reaction, or a 2008 GA diagnosis by Dr. Aylesworth. *Id.* Secondly, Respondent argued that Petitioner did not experience a GA flare after her 2015 vaccination, as her symptoms were not consistent with GA at that time. *Id.* at 14.

Because Petitioner's GA predated her vaccinations, Respondent argued that Petitioner "is limited to a significant aggravation claim." *Id.* at 16. He continued that she cannot establish, pursuant to the factors set out in *Loving,* that she experienced worsening of her GA, "which result[ed] in markedly greater disability, pain or illness, accompanied by substantial deterioration of health" post vaccination. *Id.* (citing *Loving,* 86 Fed. Cl. at 136; 42 U.S.C. § 300aa-33(4)). Respondent also argued that Petitioner did not provide preponderant evidence pursuant to the *Althen* causation factors. *Id.* at 18–21 (citing *Althen v. Sec'y of the Dept. of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). He criticized Petitioner's reliance on the Suzuki et al. study of a single case involving a patient with a GA-associated comorbidity that predated her influenza vaccination. *Id.* at 20 (citing Pet'r's Ex. 38). He argued that Petitioner offered no evidence of a GA case with an onset and manifestation similar to her clinical presentation. *Id.* at 23. He further argued that Petitioner's asserted biological mechanism, a DTH reaction, is not consistent with her clinical presentation revealed in her medical records and affidavits. *Id.* at 22. Discounting the timeline relied on by Petitioner's experts, Respondent argued that Petitioner did not establish that the flu vaccine can cause or aggravate GA generally, or that it did in this specific case. *Id.* at 24.

IV. Applicable Law

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of a hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearing and those decisions were upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that the special master acted within his discretion in denying an evidentiary hearing); *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) the petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321

(Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner did not allege a Table injury in this case; thus, she must prove that her injury was caused-in-fact by a Table vaccine or was significantly aggravated by a Table vaccine.

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs.*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory" demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006) (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 549.

Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). This may be accomplished in a number of ways. "Reliability and plausibility of . . . pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory, so as to render it credible." *See Pafford v. Sec'y of Health & Hum. Servs.,* No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380. The special master essentially must weigh and evaluate opposing evidence in deciding whether a petitioner has met their burden of proof. *See id.*; *see also Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77. The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *de Bazan,* 539 F.3d at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on*

other grounds, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014). The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant,* 956 F.2d at 1148.

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). When and if a petitioner establishes a prima facie case, the burden then shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *de Bazan*, 539 F.3d at 1354; *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" 42 U.S.C. § 300aa-13(a)(2).

This case also presents a signification aggravation claim. The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). In *Loving*, the United States Court of Federal Claims established the governing six-part test for off-Table significant aggravation claims. Petitioner must show by a preponderance of the evidence:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (adopting this as the proper legal standard for significant aggravation claims brought under the Vaccine Act).

The first two prongs of *Loving* are preliminary steps that are necessary to "evaluate the person's pre-vaccination condition and current, post-vaccination condition." *Whitecotton v. Sec'y of Health & Hum. Servs.,* 81 F.3d 1099, 1107 (Fed. Cir. 1996). Indeed, "these two steps are practically inherent in the term 'aggravation.'" *Id.* In *Sharpe,* the Federal Circuit clarified the *Loving* prongs and what is required by petitioners to successfully demonstrate a causation-in-fact significant aggravation claim. *Sharpe v. Sec'y of Health & Hum. Servs.,* 964 F.3d 1072 (Fed. Cir. 2020). *Loving* prong three requires only a comparison of a petitioner's current, post-vaccination condition, with her pre-existing, pre-vaccination condition. *Sharpe,* 964 F.3d at 1082; *Whitecotton,* 81 F.3d at 1099. A petitioner is not required to demonstrate an expected

outcome or that her post-vaccination condition was worse than such an expected outcome. *Sharpe,* 964 F.3d at 1081.

Loving prongs four, five, and six are derived from the Federal Circuit's test for off-Table actual causation cases. *See Althen*, 418 F.3d at 1281. Under *Loving* prong four, a petitioner need only provide a "medical theory causally connecting [the petitioner's] significantly worsened condition to the vaccination." *See Sharpe,* 964 F.3d at 1083; *see also Loving*, 86 Fed. Cl. at 144. In other words, a petitioner is required to present a medically reliable theory demonstrating that a vaccine "can cause a significant worsening" of the condition. *Sharpe,* 964 F.3d at 1083 (citing *Pafford ex. rel. Pafford v. Sec'y of Health & Hum. Servs.,* 451 F.3d 1352, 1356–57 (Fed. Cir. 2006)).

Loving prong five requires a petitioner to show "a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation." *Loving,* 86 Fed. Cl. at 144. In other words, a petitioner must show that the vaccination "did cause a worsening of [a petitioner's underlying disorder]." *Id.* The sixth prong of *Loving* is an adaptation of *Althen* prong three's requirement of a medically-acceptable temporal relationship. *Id.* A petitioner may be able to establish a prima facie case under *Loving* without eliminating a pre-existing condition as the cause of her significantly aggravated injury. *Id.* (citing *Walther v. Sec'y of Health & Hum. Servs.,* 485 F.3d 1146, 1151 (Fed. Cir. 2007) (noting that "the government bears the burden of establishing alterative causation . . . once petitioner has established a prima facie case")).

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.* There is no presumption that medical records are accurate and complete as to all the patient's physical conditions. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that "[b]ecause a reasonable fact finder could conclude that [the petitioner's] testimony [wa]s not inconsistent with her medical records . . . it was not arbitrary and capricious for the special master to credit [the petitioner's] testimony" over her medical records). Where there are inconsistencies, special masters are within their discretion to award contemporaneous medical records greater weight than later conflicting testimony. *See Cucuras,* 993 F.2d at 1528 (holding that the special master's reliance on contemporaneous medical records over conflicting oral testimony given after the fact was not arbitrary or capricious); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master"). In determining whether a petitioner is entitled to compensation, a special master must consider the

entire record and is not bound by any particular piece of evidence. § 13(b)(1) (stating that a special master is not bound by any "diagnosis, conclusion, judgment, test result, report, or summary" contained in the record).

V. Analysis

a. Experts

I will comment on Petitioner's experts because Petitioner curiously highlighted certain aspects of her experts' backgrounds in her briefings. For example, Petitioner noted Dr. Rostad's undergraduate degree from Harvard (with honors) and proclaimed his curriculum vitae as *res ipsa loquitur*. Pet'r's Reply at 4. It is true, as is the case with most of the medical experts we see in the Program, that both of Petitioner's experts are esteemed physicians with exemplary backgrounds. However, and more importantly, neither is an authority in GA. In fact, Dr. Rostad's curriculum vitae does not list any training, experience, or expertise in dermatology. *See generally* Pet'r's Ex. 15. Dr. Knierim was board certified in dermatology but is mostly retired from his practice in pathology. Furthermore, both physicians conceded that they have "not directly treated patients with skin problems." Pet'r's Ex. 14 at 1; Pet'r's Ex. 54 at 2. Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013). The Federal Circuit has clearly stated that special masters, as finders of fact, "are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1326. When assessing the reliability of expert testimony, special masters may consider factors such as "the qualifications, training, and experience of the expert witnesses; the extent to which their proffered opinions are supported by reliable medical research and other testimony; and the factual basis for their opinions[.]" *Lehner v. Sec'y of Health & Hum. Servs.*, No. 08-554V, 2015 WL 5443461, at *5 (Fed. Cl. Spec. Mstr. July 22, 2015) (citing *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1340 (Fed. Cir. 2014)).

Petitioner's experts had different views on the onset and development of Petitioner's disease. Because of this fundamental disagreement, and their lack of subject-matter expertise, I do not find their arguments on such issues persuasive. Instead, I am more persuaded by their explanations, opinions, and conclusions made with support in the factual record or medical literature. Accordingly, I will award assertions without citations to the record or supporting authority less weight.

b. Granuloma Annulare Symptom Onset

Petitioner's GA diagnosis is not in dispute, but the initial onset is a main point of contention. Petitioner asserted in her petition that her GA initially presented as unrelenting and

incurable itching in November of 2015 and developed into a rash in early 2016.[74] According to Petitioner's affidavits and medical records, the itching presented first, approximately two to three weeks following her November 9, 2015 vaccination. Ultimately, Petitioner developed a rash that she first reported during her April 15, 2016 visit to urgent care. However, the record shows Petitioner's pruritus predated her rash by several months.

Dr. Rostad also identified Petitioner's first symptom of GA as itching that "began gradually approximately two to three weeks after receiving the November 2015 vaccine." Pet'r's Ex. 14 at 9. Experts from both parties described the clinical presentation of GA in their reports. Dr. Rostad described GA as erythematous papules. Pet'r's Ex. 14 at 7. He cited medical literature and Dr. Cyr's definition indicating that GA can be localized or generalized. Pet'r's Ex. 17 at 1. Dr. Boos's definition was similar, and he wrote that GA presents as "arciform to annular plaques that can range from skin colored to purple." Resp't's Ex. A at 6. Dr. Boos characterized the condition as asymptomatic. *Id.* Dr. Cyr also noted that GA is generally asymptomatic but may be accompanied by mild pruritus. Pet'r's Ex. 17 at 1. Dr. Rostad agreed that itching has an association with GA but acknowledged that pruritus "is a nonspecific clinical symptom." Pet'r's Ex. 14 at 9. Neither of the experts nor the filed medical literature includes severe itching as a diagnostic symptom or even common characteristic of GA. In one of Petitioner's filed articles, Dr. Moses noted that pruritus occurs with several diseases, but he did not mention GA. Pet'r's Ex. 24 at 4.

It is unclear why Dr. Rostad identified Petitioner's itching as the onset symptom of her GA. The five-month time lapse between the pruritis onset and the appearance of the rash further undermines any argument that the two are related or indicative of the same condition. Given that itching is not identified by the experts or the medical literature as a diagnostic symptom of GA; that Petitioner's itching was described as severe and not the mild pruritis that has been seen with GA; and that Petitioner's itching and her rash manifested months apart, there is not preponderant evidence that Petitioner's itching is connected to her GA. Therefore, there is not preponderant evidence that Petitioner's GA manifested with her pruritus, two-to-three weeks after her 2015 flu vaccination.

Petitioner's first post-vaccination, telltale GA rash, consistent with the medical literature and expert testimony, appeared in late March/early April of 2016. A medical record from April 15, 2016, described an erythematous, maculopapular rash on Petitioner's abdomen and legs that was pruritic. Pet'r's Ex. 3 at 16. Petitioner's complete medical records and statements provide consistent evidence of the approximate five-month gap between her 2015 flu vaccination and the appearance of the rash. During this time, Petitioner suffered from a known intervening cause of GA. Indeed, Petitioner was diagnosed with viral exanthem in April of 2016, and the medical literature filed by both parties identifies viruses as potential causes of GA. *See* Pet'r's Ex. 58; Resp't's Ex. A, Tab 12. Petitioner's own accounts are also consistent with her treater's ultimate

[74] Within Dr. Knierim's supplemental expert report, there is an account of a statement wherein Petitioner stated that she was first treated for GA by Dr. Aylesworth in 2008. Pet'r's Ex. 61 at 2. Dr. Knierim relied on this statement to argue that Petitioner's flu vaccinations in 2015 and 2016 significantly aggravated her preexisting GA. Despite filing this report, Petitioner did not assert this specific significant aggravation claim. Likewise, she did not acknowledge in her motion for a ruling on the record that her GA predated her 2015 vaccination. *See generally* Pet'r's Mot.

opinion that Petitioner's rash flared whenever she had a virus. Pet'r's Ex. 2 at 1; Pet'r's Ex. 4 at 2, 9–10.

Petitioner continued to complain of red bumps on her chest and flanks in August of 2016 and described a history of psoriasis to her treater during a visit that month. Pet'r's Ex. 4 at 1. Following Petitioner's November 7, 2016 flu shot, however, there is another extended period without medical records. She stated in her affidavit that at the time of her 2016 vaccination, she was recovering from a viral infection and covered in an itchy rash. Pet'r's Ex. 2 at 1–2. Again, in June of 2017, Petitioner sought treatment for itchy, red bumps all over her entire body, present since February of 2017. Pet'r's Ex. 4 at 2. Her treater observed red, eroded papules on her chest, axilla, arms, and legs. *Id.* at 6. Petitioner told her treater that her symptoms get worse following a flu shot or cold. All of these descriptions are similar. Petitioner argued these flares are all manifestations of her GA that was only diagnosed by Dr. Aylesworth following her June 17, 2017 biopsy. *Id.* at 3. However, there is preponderant evidence that these flares followed viral infections that were closer in time to Petitioner's reactions than the vaccines in question.

In Dr. Knierim's first expert report, he reiterated Petitioner's argument that her GA began post vaccination and opined that "other skin lesions prior to November 2015 [are] not relevant." Pet'r's Ex. 54 at 5. Notably, in his second expert report, Dr. Knierim rescinded his prior assertion and admitted that GA "was present in [Petitioner] years prior to the 2015 and 2016 influenza vaccinations." Pet'r's Ex. 61 at 1. At no point in any of Petitioner's filings does she address Dr. Knierim's reversal or the basis for his change in opinion. Petitioner's gross omission undermines the general credibility of her entire claim, and specifically her causation-in-fact theory.

Furthermore, Petitioner's medical records are consistent with Dr. Knierim's reversal and document symptoms consistent with GA on several occasions pre vaccination, as early as 2010 and thereafter. Most notably, Petitioner's 2010 annual exam documented that her "lower legs [presented] with granuloma annularis [sic]." Pet'r's Ex. 9 at 4. Indeed, Petitioner admitted to Dr. Knierim that she was diagnosed with GA by 2008 after lesions developed on her legs in 2007. Pet'r's Ex. 61 at 2. Respondent's expert, Dr. Boos, noted that GA is rare, and "it is extremely unlikely that a non-dermatologist [(such as the treater conducting Petitioner's annual exam in 2010)] would use this term without a patient having received this diagnosis previously." Resp't's Ex. A at 9–10. I agree. This argument is further supported by Dr. Knierim's assertion that a pathologist and dermatologist were necessary to identify Petitioner's correct diagnosis of disseminated GA in 2017. Pet'r's Ex. 54 at 5. Furthermore, in 2011, Petitioner described "chronic skin problems and rashes that pop[ped] up here and there" although she described them as "eczema and dermatitis." Pet'r's Ex. 9 at 5. A November 21, 2012 record, from Petitioner's annual exam, noted Petitioner's "forearms and upper left arm are with several areas of red, flat, macular-type lesions." *Id.* at 3. Given Petitioner's clinical course, it appears more likely than not that she was properly diagnosed with GA years prior to the flu vaccines at issue.

In her second affidavit, Petitioner explained that she "had skin issues in the past," but they were "not the same type" as her post-vaccination injury. Pet'r's Ex. 13 at 1. She continued that her previous diagnoses included "eczema or contact dermatitis that were easily treated with topical creams." *Id.* However, Petitioner did not submit medical records that clarify the nature of her pre-vaccination skin conditions. The catalyst for Petitioner's skin conditions, including her GA, has

varied from stress to a viral infection. The descriptions of her physical manifestations and rashes, however, have remained consistent. Petitioner has not presented preponderant evidence that her GA developed after her 2015 flu vaccine. The medical records provide evidence that Petitioner suffered from GA as early as 2010.

c. Pre-vaccination Condition: *Loving* prong one

Petitioner has maintained throughout the course of this claim that she developed GA as a result of her 2015 flu vaccination. In her first affidavit, she stated her belief that her November 9, 2015 vaccination was the cause of her injuries. Pet'r's Ex. 2 at 5. Furthermore, Petitioner asserted in her motion for a ruling on the record that "her GA had not been formally diagnosed" prior to her 2016 flu vaccination. Pet'r's Mot. at 2. As previously discussed, however, Dr. Knierim acknowledged that Petitioner suffered from GA pre vaccination. Also as previously noted, Petitioner's filings support Dr. Knierim's opinion and provide some evidence to assess her pre-vaccination condition pursuant to *Loving* prong one. Petitioner noted in her affidavit that she has a history of skin conditions that she could treat with topical creams. Petitioner's medical records document pre-vaccination rashes on her lower legs, forearms, and upper left arm. She regularly filled a prescription for betamethasone dipropionate, a glucocorticoid steroid, for such rashes characterized as chronic eczema and dermatitis, that would "pop up here and there." *Id. Dorland's* explains that this ointment is used to relieve inflammation and pruritus in varied dermatological conditions.[75] Dr. Cyr noted in her article on the diagnosis and management of GA that "treatment is usually not necessary," but some patients that insist on treatment receive topical corticosteroids. Pet'r's Ex. 17 at 4. Petitioner has established with preponderant evidence that her pre-vaccination skin conditions were reasonably controlled with her prescribed medication and home remedies, including calamine lotion and aloe vera.

d. Post-vaccination Condition/ Significant Aggravation: *Loving prong two*

Petitioner argued in her motion for a ruling on the record that her claim is primarily a but-for causation claim specific to her 2015 vaccination. Her secondary significant aggravation claim alleges that the condition she developed in 2015 was exacerbated by her 2016 vaccination. This claim stands in direct contrast to Dr. Knierim's argument that Petitioner's 2015 vaccination significantly aggravated her pre-existing GA. Despite Petitioner's insistence that her significant aggravation claim is limited only to the 2016 vaccine, I will consider her expert's argument and any supporting evidence to decide entitlement. Petitioner's condition during the time between her vaccinations (November 9, 2015 – November 7, 2016) will therefore be assessed for: 1) a significant aggravation of her pre-existing GA following her 2015 vaccination and 2) a significant aggravation of her GA condition following her 2016 vaccination.

i. Pre-existing GA aggravated by 2015 vaccination

Petitioner did not present evidence of an immediate reaction following her 2015 vaccination. She did not seek treatment and does not have contemporaneous medical records that document the extent and specific onset of itching. In her affidavit, she described the gradual development of an increasingly worsening pruritus, approximately two to three weeks following

[75] *See supra*, note 7 (defining betamethasone dipropionate).

her November 9, 2015 flu vaccination. Petitioner also described a rash that developed in March of 2016. This rash appeared several months after the 2015 vaccine and, per Petitioner, followed a cold. Petitioner noted that the topical treatments and home remedies she used for previous skin conditions were ineffective on this rash. Medical records from treatment in April of 2016 revealed a rash on Petitioner's trunk and limbs that was diagnosed as viral exanthem. Petitioner also filed photographs that she asserts depict the rash on her abdomen and one of her extremities in April of 2016. The clarity of the images is poor, but some discoloration of the skin is visible. Petitioner's former colleague, Ms. Bessette, stated in her affidavit that Petitioner's rash following her 2015 vaccination was red and blotchy with bleeding scratch marks. Petitioner was prescribed an antihistamine and steroids, but she told treaters that she would continue to use medications previously prescribed to treat her pre-vaccination skin issues. When Petitioner sought dermatological treatment in August of 2016, her rash was in remission but not completely gone. She disclosed occasional, recurring break outs following viral illnesses.

Without photos, dermatological records, or additional medical records from 2010 through 2015, or from the months immediately following her November 9, 2015 vaccine, it is difficult to compare the severity of Petitioner's skin condition pre vaccination to post vaccination. However, Petitioner asserted that her GA worsened in March of 2016, and medical records document an extensive rash in April of 2016. The increased severity during that timeframe is supported by her ultimate decision to seek professional medical treatment in April of 2016. This worsening more likely than not occurred after her November 2015 vaccination. Therefore, Petitioner has presented preponderant evidence that her skin condition worsened after her 2015 flu vaccination.

ii. 2015 GA aggravated by 2016 vaccine

At the time that Petitioner received her November 2016 flu vaccination, she was already suffering from an itchy rash. Petitioner admitted that this rash appeared in the wake of a viral infection. Post vaccination, Petitioner reported persistent unbearable itching, disfiguring, and scarring lesions present since February 2017, that did not respond to treatment. *See, e.g.*, Pet'r's Ex. 2 at 3; Pet'r's Ex. 4 at 2. Petitioner's submitted photos dated May of 2017, provide clearer images of the extent of the rash and nodules consistent with the descriptions in the expert reports and medical literature as characteristic of GA. Dr. Aylesworth observed this rash and ordered a skin biopsy in June of 2017. Pet'r's Ex. 4 at 2. The biopsy revealed thickening of the skin and underdevelopment of the top layer skin cells. This is consistent with Petitioner's statement that she had multiple skin irritations that bled from her scratching around that time. Petitioner was prescribed methotrexate from July 2017 through 2019, and she reported that it effectively treated her flares. By January of 2019, Petitioner told Dr. Aylesworth that she used steroid cream rarely and did not need further treatment.

Petitioner asserted that the itching and the rashes she experienced following her November 2016 vaccination were worse than she had ever experienced. Pet'r's Ex. 2 at 3. However, her description of the rash that appeared in March of 2016 (before her 2016 vaccination) is similar to her description of other rashes that developed at the time of her 2016 vaccination and thereafter. For instance:

1. Petitioner presented to urgent care on April 15, 2016, complaining of a rash following an URI in March, one month earlier. She described the itching as tear-inducing and noted that none of her usual remedies worked. She sought treatment from a dermatologist in August of 2016, with continued complaints of a rash recurring every six-to-eight-weeks since her URI five months prior.
2. At the time of her flu vaccine in November of 2016, Petitioner asserted that she had already developed a rash following another URI. Petitioner did not say how long this flare lasted, and there are no medical records during this time. In an email to her employer two weeks post vaccination, Petitioner described the rash and agonizing itching, but indicated she would not seek treatment.
3. In June of 2017, seven months later, Petitioner saw Dr. Aylesworth and complained of a rash present since February of 2017. She reported that the rash increased in severity following her flu shots and colds. Petitioner stated the pruritus drove her to scratch until she bled with no relief from medication or home remedies.

Petitioner described her rash as having an unbearable itching, red bumps, and a resistance to topical treatments in all instances. *See, e.g.*, Pet'r's Ex. 3 at 15; Pet'r's Ex. 5 at 1; Pet'r's Ex. 2 at 2; Pet'r's Ex. 4 at 2. These three documented instances of Petitioner's skin condition reveal a history of flares before and after her 2016 vaccination that are similar in severity. I do not find preponderant evidence that Petitioner's flares changed for the worse following her 2016 vaccination, or resulted "in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4).

e. General Causation: *Althen* prong one / *Loving* prong four

Petitioner's expert Dr. Rostad acknowledged that the trigger for GA is unknown; however, he hypothesized that GA is the result of an abnormal immune response triggered by vaccines. I must note that Dr. Rostad, like Petitioner, maintained that Petitioner did not suffer a significant aggravation until her 2016 flu vaccine. His proposed biological mechanism involves an initial manifestation of the disease caused by the 2015 flu vaccine and not a significant aggravation. Despite my findings with respect to *Loving* factors one through three, to ensure complete consideration of Petitioner's claim, I will analyze her cause-in-fact mechanism.

Dr. Rostad identified GA as a lymphocyte-mediated hypersensitivity type IV or DTH reaction caused by an antigen trigger. Dr. Rostad continued that GA is a manifestation of a DTH reaction to collagen or elastin destruction. Respondent's expert, Dr. Boos, agreed that "it has been proposed that GA represents a [DTH] reaction." Resp't's Ex. A at 7. Dr. Rostad explained that the antigen incites the immune system, including macrophages that release proinflammatory cytokines, and that this release causes damage to collagen or elastin in the lesions. Petitioner filed articles that explain this DTH pathology. Pet'r's Exs. 22–23.

While Petitioner provided evidence that GA can be caused by a DTH reaction, she did not, however, file articles that explain the pathogenesis of a flu-vaccine induced DTH. Dr. Rostad identified the flu vaccine (or one of its components) as an example of a triggering antigen, but he did not explain his basis for this assertion or file any supporting literature. Aside from his discussion of adjuvants, which will be addressed in more detail below, Dr. Rostad did not identify

any flu vaccine component that would result in a local DTH reaction. Petitioner does not have to provide a specific mechanism, but it must be detailed enough to apply to the specific vaccine and injury in this case. Otherwise, any vaccination, by nature of its purpose to illicit an immune response, could be asserted as the cause of any autoimmune disease that later developed in an individual. Indeed, this reasoning would nullify but-for causation in its entirety. *See W.C. v. Sec'y of Health & Hum. Servs.,* 704 F.3d 1352, 1360 (2013) (finding that a petitioner cannot prevail by simply invoking a biological term, or by showing that the mechanism is a valid theory to explain how *other* triggers may have induced *other* diseases and determining that a petitioner must produce additional evidence that the mechanism can cause that vaccine to cause a specific disease); *Caves v. Sec'y of Health & Hum. Servs.,* 100 Fed. Cl. 119, 135 (2011), *aff'd*, 463 F. App'x. 932 (2012); *McKown v. Sec'y of Health & Hum. Servs.,* No. 15-1451, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019).

Of the filed medical literature, only one case study discussed the development of GA following the flu vaccine. The Suzuki et al. article revealed that the patient also suffered from diabetes mellitus, a disease the author suggested promotes granuloma formation. Pet'r's Ex. 38 at 1. Other articles filed by both Petitioner and Respondent discuss GA following other vaccinations, including tetanus, live rubella, and several following the BCG vaccine. Dr. Rostad did not explain how these vaccines are analogous to the flu vaccine, such that the articles would be instructive for a case involving the flu vaccine. I must stress that the filing of medical literature is not a requirement in order to establish causation in the Program. However, to the extent it is filed and relied upon, the authors' opinions, suggestions, and omissions may be considered. *See Knudsen*, 35 F.3d at 549; *Andreu*, 569 F.3d at 1378–79 (citing *Capizzano*, 440 F.3d at 1325–26).

To the extent that Dr. Rostad presented a biological mechanism specific to the flu vaccine, it was limited to the ASIA theory that Petitioner ultimately disavowed. Petitioner did not receive an adjuvanted vaccine in this case, and that argument is therefore rightly characterized by Petitioner as irrelevant. Indeed, as stated previously in this Decision, Petitioner stated in no uncertain terms, that ASIA was not her asserted theory of causation. This is likely an informed choice, given the breadth of claims in the Program's history that have unsuccessfully relied on ASIA, also previously cited.[76]

Dr. Rostad did not present any evidence of a biological mechanism for the alleged 2016 significant aggravation. If he had, it may also have been applicable to Petitioner's symptoms following the 2015 vaccination. Dr. Knierim likewise did not identify any biological mechanism. Petitioner has not provided preponderant evidence that the flu vaccine can cause or significantly aggravate GA.

f. Specific Causation: *Althen* prong two / *Loving* prong five

I have already explained that Petitioner has not presented preponderant evidence that her GA first manifested after her 2015 vaccination. Indeed, the preponderant evidence of her GA prior to the first vaccination at issue precludes a successful but-for causation claim. *Shalala v. Whitecotton,* 514 U.S. 268, 274–75 (1995) (a Vaccine Act claimant who demonstrates she experienced symptoms of injury after receipt of vaccination does not succeed in her claim if the

[76] *See supra*, note 61.

evidence indicates that she had symptoms of injury before her vaccination); *Locane v. Sec'y of Health & Hum. Servs.,* 99 Fed. Cl. 715, 727 (2011), *aff'd*, 685 F.3d 1375 (Fed. Cir. 2012) (finding that the petitioner's Crohn's disease began prior to her vaccinations and therefore vaccine causation could not be established). Furthermore, Petitioner has not submitted preponderant evidence of a viable mechanism to establish that a flu vaccination can cause or significantly aggravate GA. The lack of preponderant evidence of worsening symptoms following the second vaccination at issue in this case also precludes Petitioner's asserted secondary claim of significant aggravation. Petitioner has, however, been able to establish by preponderant evidence that her pre-existing GA worsened following her 2015 flu vaccination. Therefore, despite the lack of a significant aggravation mechanism, I will complete consideration of the record to determine if Petitioner provided preponderant evidence that her November 9, 2015 flu vaccine significantly aggravated her preexisting GA. A comparison of Petitioner's clinical presentation to her expert Dr. Rostad's hypothesis further illustrates the incongruity of his argument. Dr. Rostad began by noting that Petitioner's health had been stable up to November 9, 2015. It is correct that Petitioner's filed medical records do not include a formal diagnosis of GA or any other severe skin conditions prior to her 2015 vaccination. However, Petitioner's records do not include dermatological records that could provide context for the December 15, 2010 GA notation from her physical exam. Also, Petitioner has had a continuous prescription for a corticosteroid for many years and reported skin conditions exacerbated by stress and illness. While it can be stated that Petitioner did not suffer from severe medical conditions, the health of her skin was only stable insofar as she maintained her steroid treatments and avoided her self-identified triggers, including stress and viral illness.

Dr. Rostad then opined that some unknown antigen stimulated Petitioner's immune system, first locally, and that the reaction expanded within two-to-three weeks into systemic itching. In her affidavits and reports to medical professionals, however, Petitioner never described a localized reaction to either vaccine. She described itching all over her upper body, noting that she could not wear tight clothing. As explained previously, this itching predated Petitioner's rash by several months, and Petitioner has not presented preponderant evidence to connect the symptoms. Five months following her November 2015 vaccination, medical records document a rash covering Petitioner's abdomen, back, and legs. Petitioner, at the time, identified the 'unknown' antigen as a URI that had infected her entire family. In fact, her diagnosis at that time, viral exanthem, is consistent with a viral pathology rather than an adverse reaction to vaccination.

Despite no evidence of a localized, immune response at the injection site, Dr. Rostad asserted that this occurrence triggered a DTH reaction in the form of GA. He offered in support that his "theory is based on knowledge of the pathogenesis of DTH and GA." Pet'r's Ex. 14 at 15. This assertion is unhelpful, as Dr. Rostad acknowledged that the pathogenesis of GA is unknown. *Id.* at 8. Furthermore, Petitioner's clinical presentation is uncharacteristic of even Dr. Rostad's descriptions of localized GA following the flu vaccine. The McNeil and DeStefano article identified rashes as the most common sign of a vaccine-induced DTH reaction; however, the authors asserted that DTH reactions "are often self-limiting conditions that do not contraindicate administration of future doses." Pet'r's Ex. 48 at 2. This statement is contrary to Petitioner's claim that her condition "has become more severe each time she has had a flu shot." Pet'r's Ex. 4 at 2. The initial pruritic symptoms, delayed symptom onset, and the presence of intervening viral antigens all overwhelmingly disrupt any logical sequence of cause and effect in Petitioner's case.

Petitioner is therefore unable to establish by preponderant evidence that her 2015 flu vaccination significantly aggravated her GA.

g. Timing: *Althen* prong three / *Loving* prong six

Although Petitioner has been unable to establish by a preponderant standard that her GA was aggravated by her 2015 flu vaccine, I will complete the *Loving* analysis and determine if there is an appropriate temporal relationship between Petitioner's 2015 flu vaccination and the manifestation of the worsening of her GA flares. Dr. Rostad filed literature on DTH reactions that noted occurrences within days and up to two to three weeks following exposure. Pet'r's Ex. 48 at 2. He also asserted that a GA DTH reaction could occur approximately 21–28 days following contact with the offending antigen, which in this case would be an unknown component of the flu vaccine. Even assuming that approximately one month is an acceptable temporal relationship between vaccination and symptom onset, Petitioner's case does not fall within those parameters. Petitioner's alleged post-vaccination injury, GA, did not manifest until five months following her 2015 vaccination. This lapse is simply too long to fit within Petitioner's asserted mechanism. Petitioner has not presented preponderant evidence of an appropriate temporal relationship between her November 9, 2015 flu vaccine and GA flare in March of 2016.

VI. Conclusion

Petitioner has undergone a frustrating and trying experience, and I have reviewed the entire record in an effort to understand what happened to her. After careful consideration, I find that Petitioner has not provided evidence that her 2015 and/or 2016 flu vaccinations caused her to develop or significantly aggravate her GA. Therefore, her claim must be **DISMISSED.**[77]

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

[77] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.